

(12) **United States Patent**  
**Miller**

(10) **Patent No.:** **US 9,241,911 B2**  
(45) **Date of Patent:** **\*Jan. 26, 2016**

(54) **MULTI-PHASE, MULTI-COMPARTMENT, CAPSULAR DELIVERY APPARATUS AND METHODS FOR USING SAME**

(2013.01); *A61J 3/072* (2013.01); *A61J 3/074* (2013.01)

(71) Applicant: **Fred H. Miller**, Tampa, FL (US)

(58) **Field of Classification Search**  
CPC ... *A61K 45/06*; *A61K 9/4808*; *A61K 9/4833*;  
*A61J 3/074*; *A61J 3/072*  
See application file for complete search history.

(72) Inventor: **Fred H. Miller**, Tampa, FL (US)

(\* ) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(56) **References Cited**

U.S. PATENT DOCUMENTS

6,380,175 B1 *	4/2002	Hussain et al. ....	514/100
7,670,612 B2 *	3/2010	Miller .....	424/400
8,361,497 B2 *	1/2013	Miller .....	424/451

This patent is subject to a terminal disclaimer.

OTHER PUBLICATIONS

Tramèr et al., "Cannabinoids for the control of chemotherapy induced nausea and vomiting: quantitative systematic review" *BMJ* 2001; 323: 16.\*

(21) Appl. No.: **14/036,521**

(22) Filed: **Sep. 25, 2013**

\* cited by examiner

(65) **Prior Publication Data**

US 2014/0212482 A1 Jul. 31, 2014

**Related U.S. Application Data**

*Primary Examiner* — Aradhana Sasan

(63) Continuation of application No. 13/746,743, filed on Jan. 22, 2013, now abandoned, which is a continuation of application No. 12/689,669, filed on Jan. 19, 2010, now Pat. No. 8,361,497, which is a continuation of application No. 10/804,576, filed on Mar. 19, 2004, now Pat. No. 7,670,612, which is a continuation-in-part of application No. PCT/US03/10816, filed on Apr. 9, 2003.

(74) *Attorney, Agent, or Firm* — Hudak, Shunk & Farine Co. LPA

(60) Provisional application No. 60/371,448, filed on Apr. 10, 2002.

(57) **ABSTRACT**

A multi-compartment capsule, comprising, a first receiving chamber comprising at least one ingredient having a first physical state, wherein said ingredient is selected from the group consisting of a nutraceutical, a vitamin, a dietary supplement and a mineral; and a second receiving chamber comprising at least one ingredient having a second physical state, wherein said ingredient is selected from the group consisting of a nutraceutical, a vitamin, a dietary supplement and a mineral; wherein said first physical state of said ingredient of said first receiving chamber being different from said second physical state of said ingredient of said second receiving chamber; and said ingredient of said first receiving chamber being different from said ingredient of said second receiving chamber.

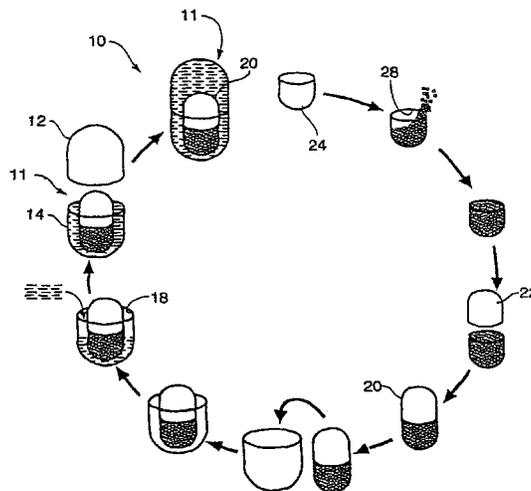
(51) **Int. Cl.**

<i>A61K 9/48</i>	(2006.01)
<i>A61K 45/06</i>	(2006.01)
<i>A61J 3/07</i>	(2006.01)
<i>B29C 39/10</i>	(2006.01)

(52) **U.S. Cl.**

CPC ..... *A61K 9/4808* (2013.01); *A61K 9/4833* (2013.01); *A61K 45/06* (2013.01); *B29C 39/10*

**17 Claims, 13 Drawing Sheets**



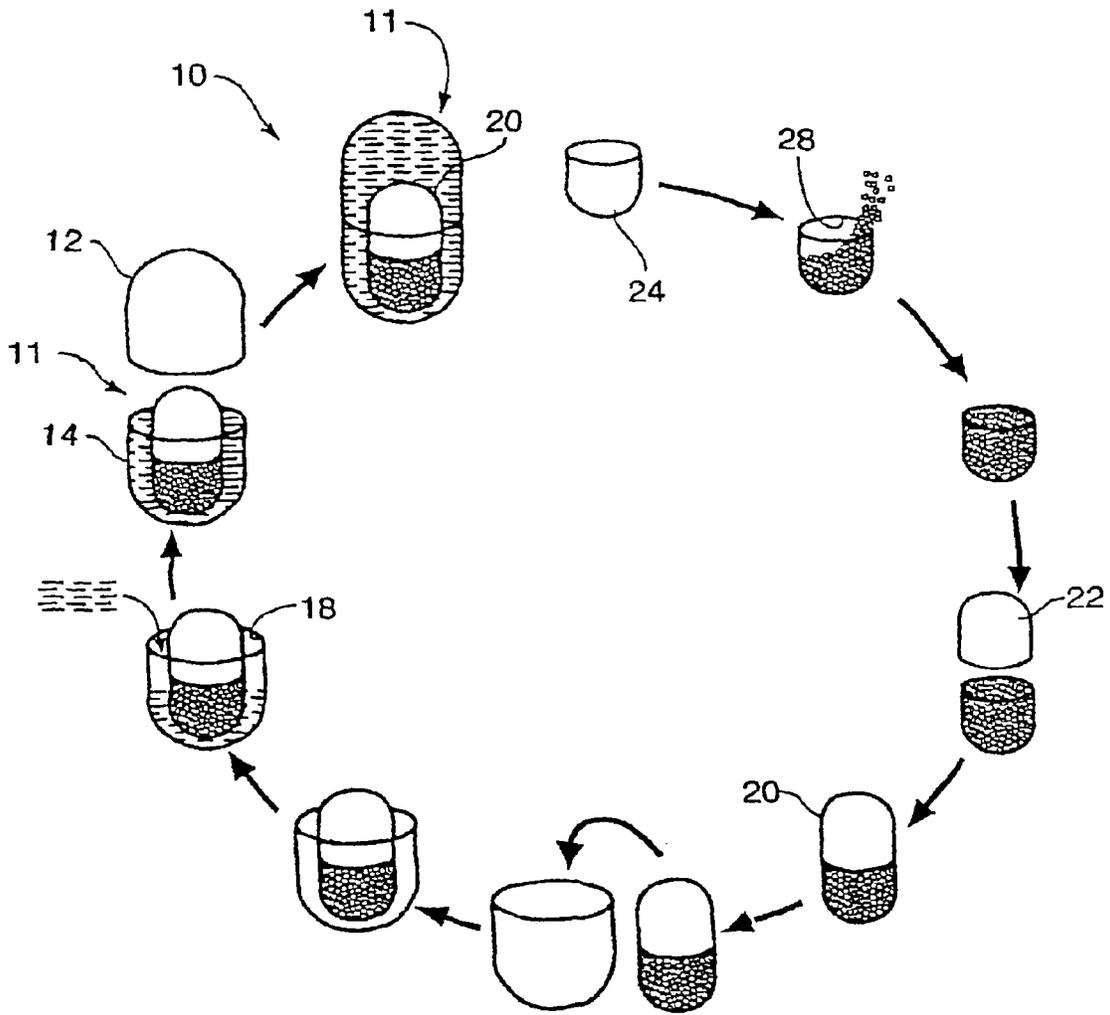


FIG. 1

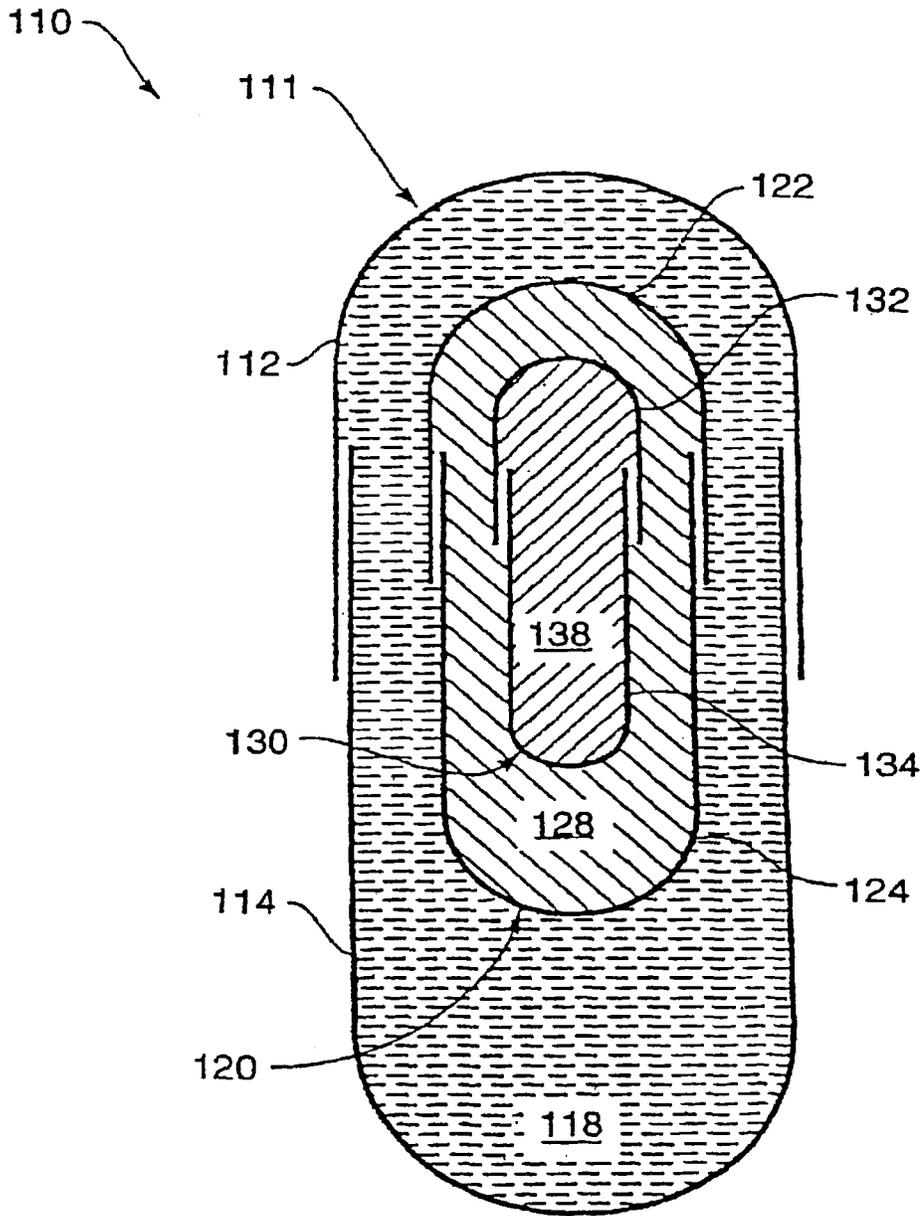


FIG. 2

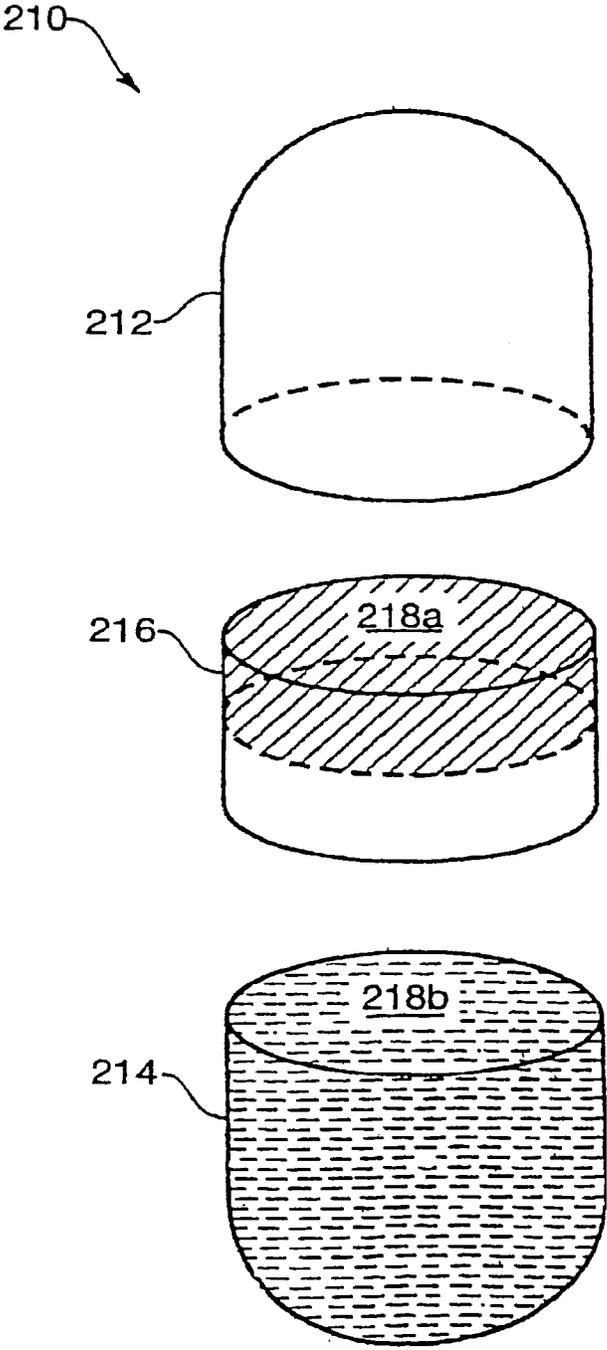


FIG. 3

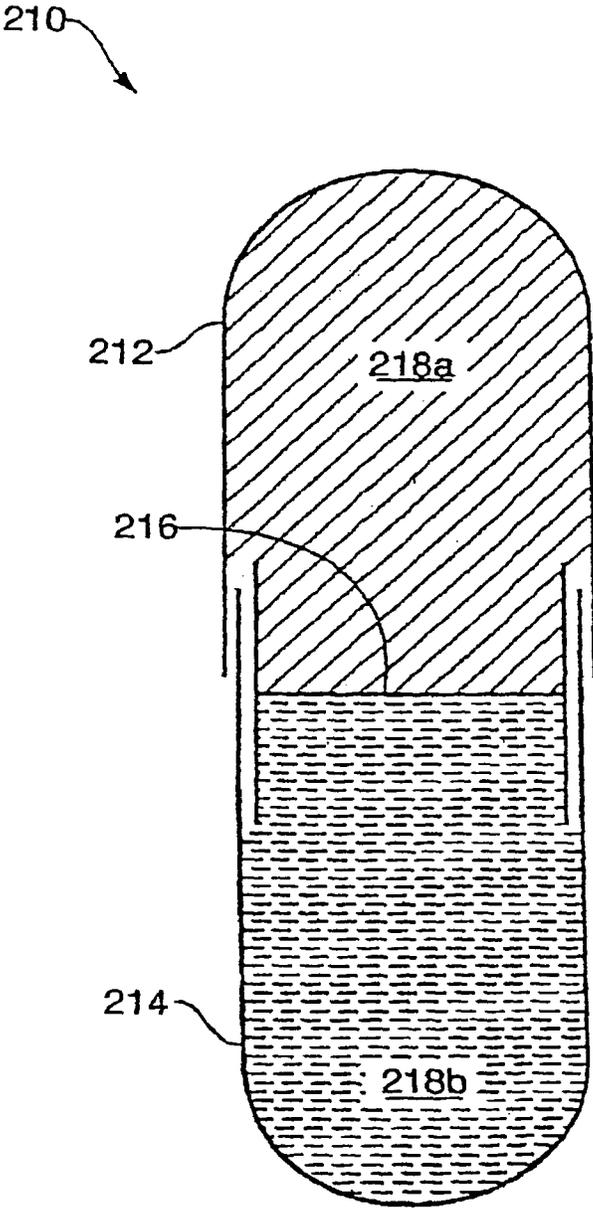


FIG.4

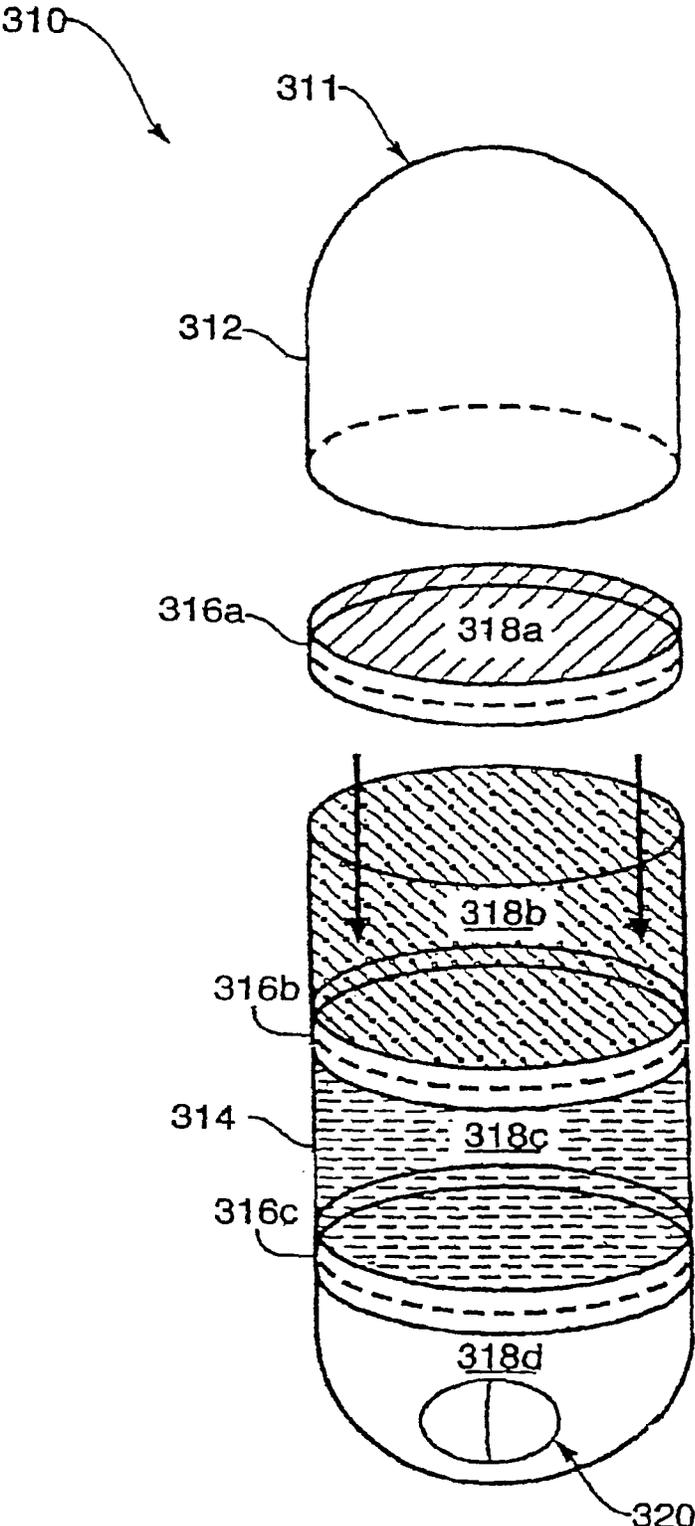


FIG. 5

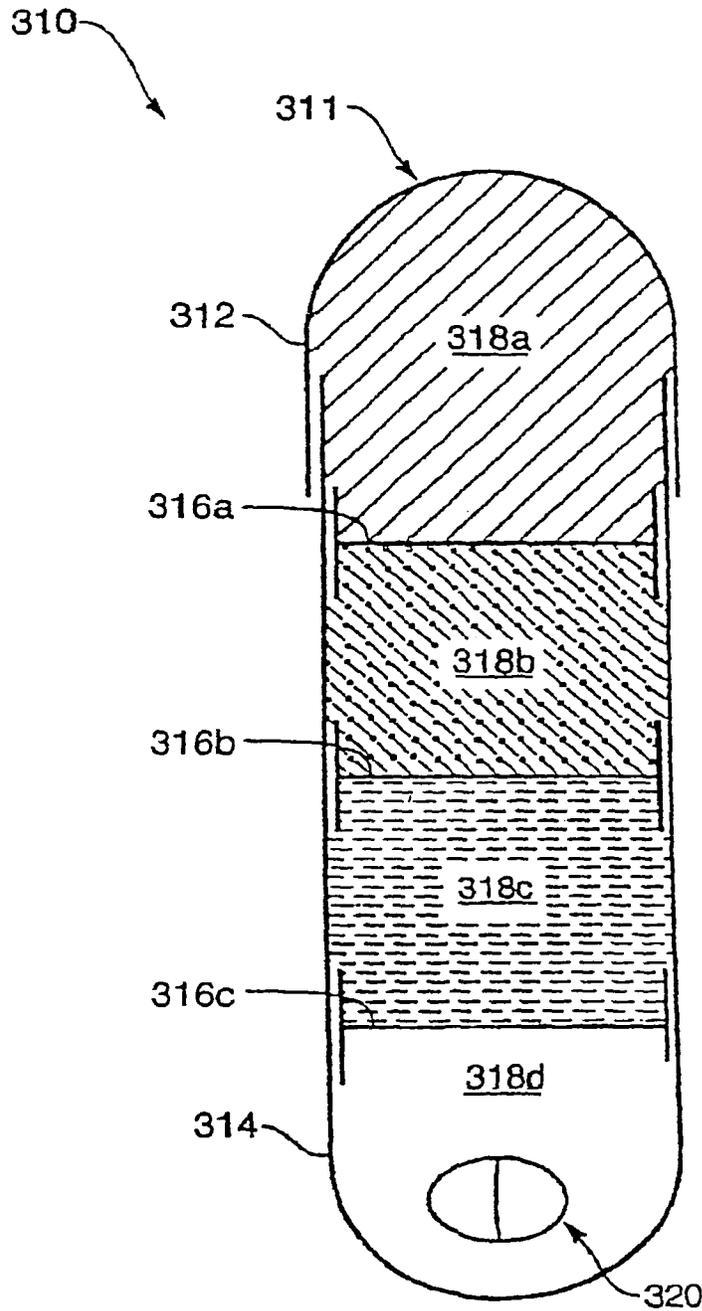


FIG. 6

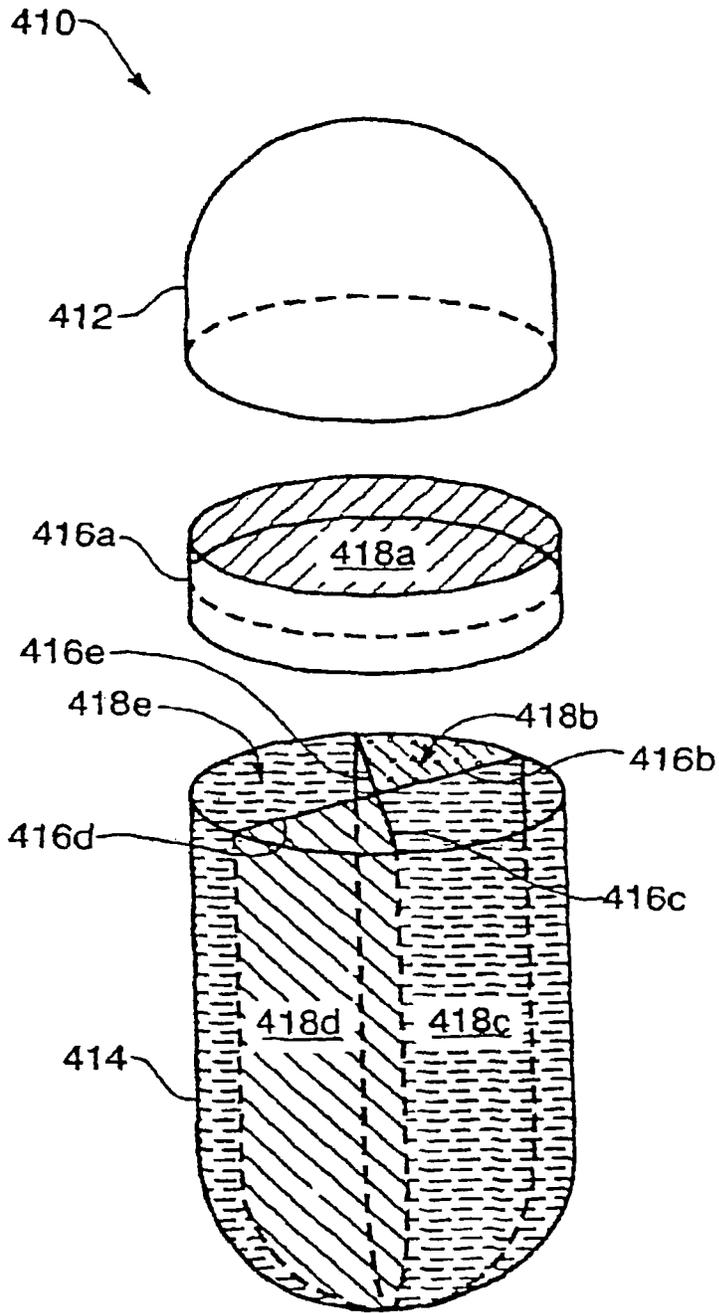


FIG. 7

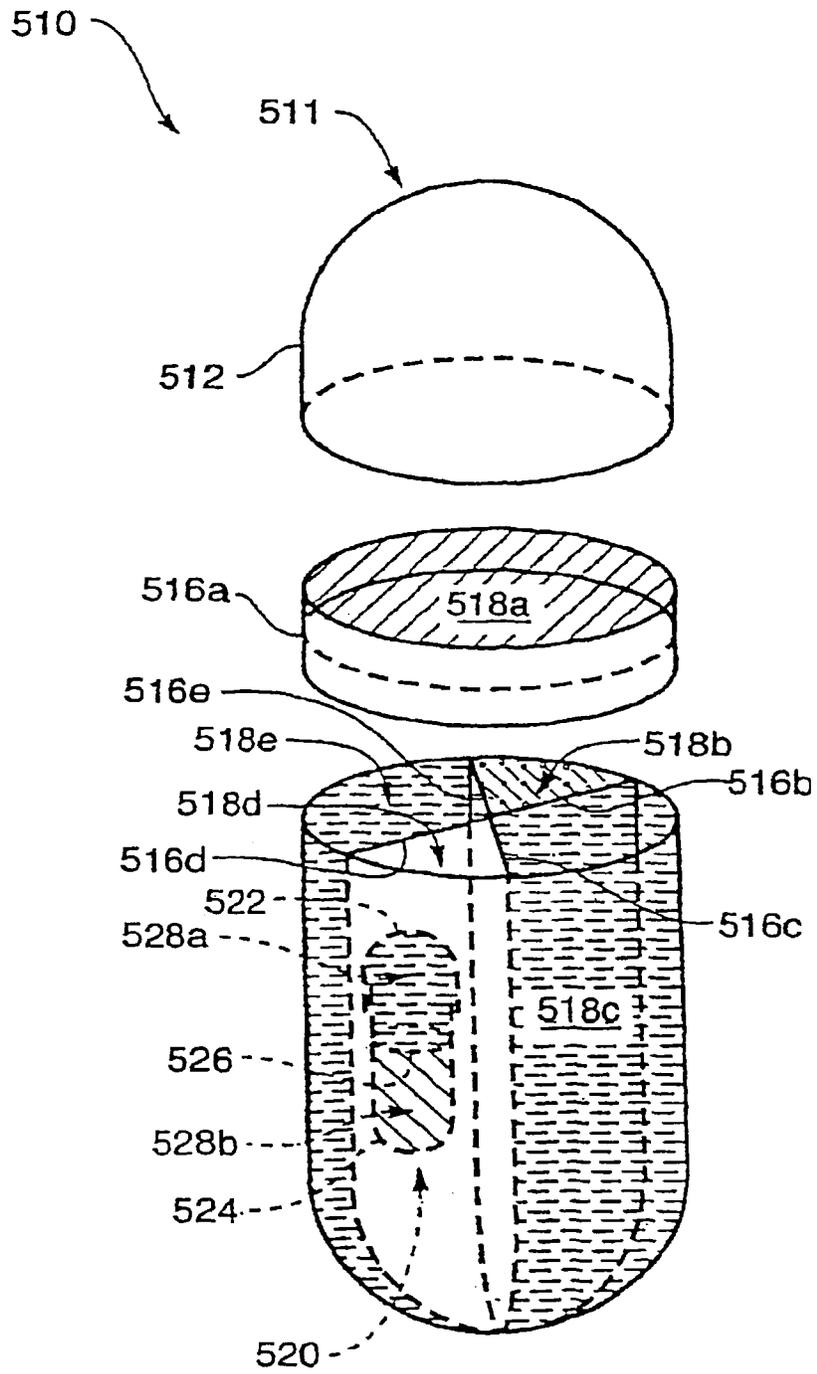


FIG.8

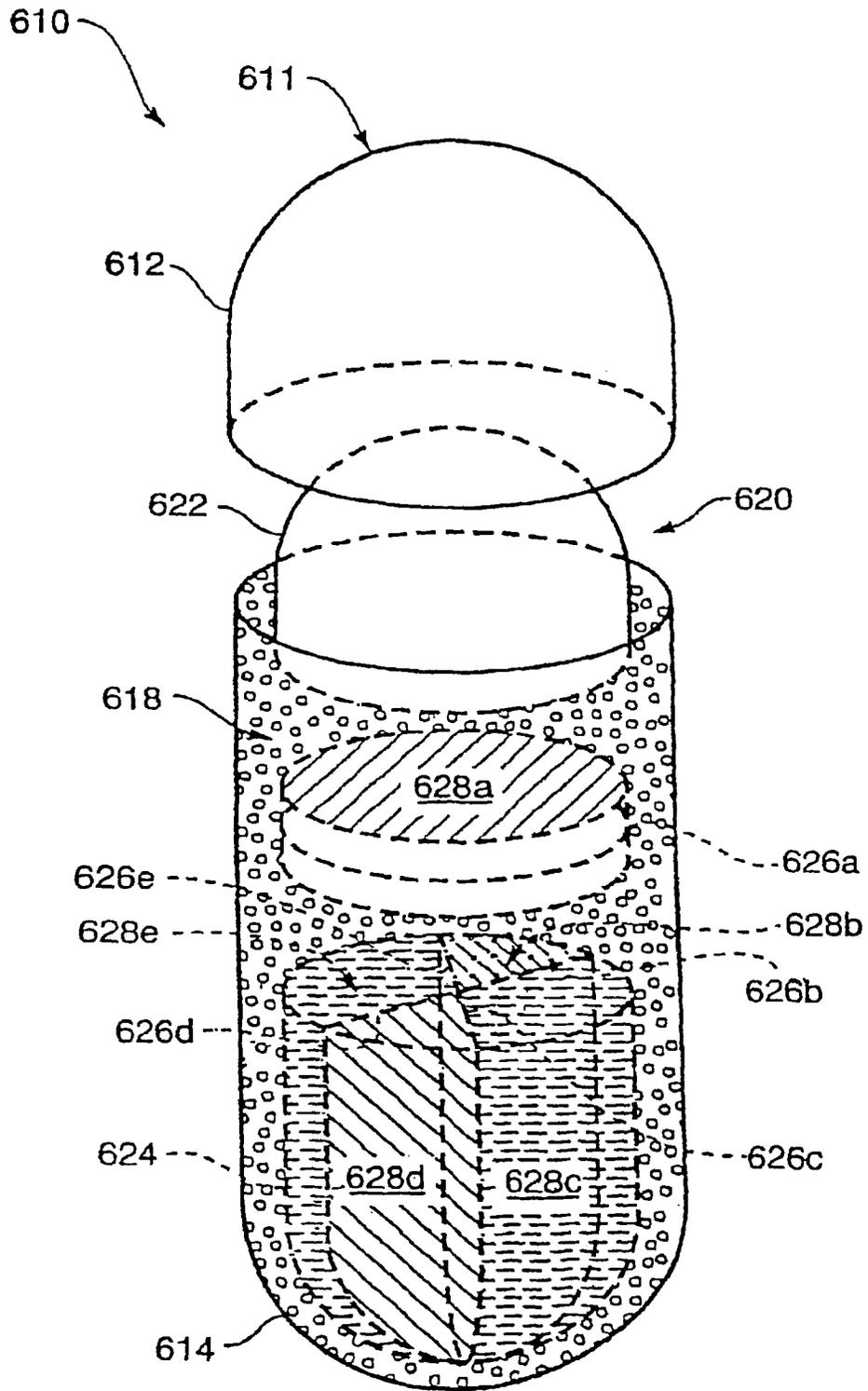


FIG. 9

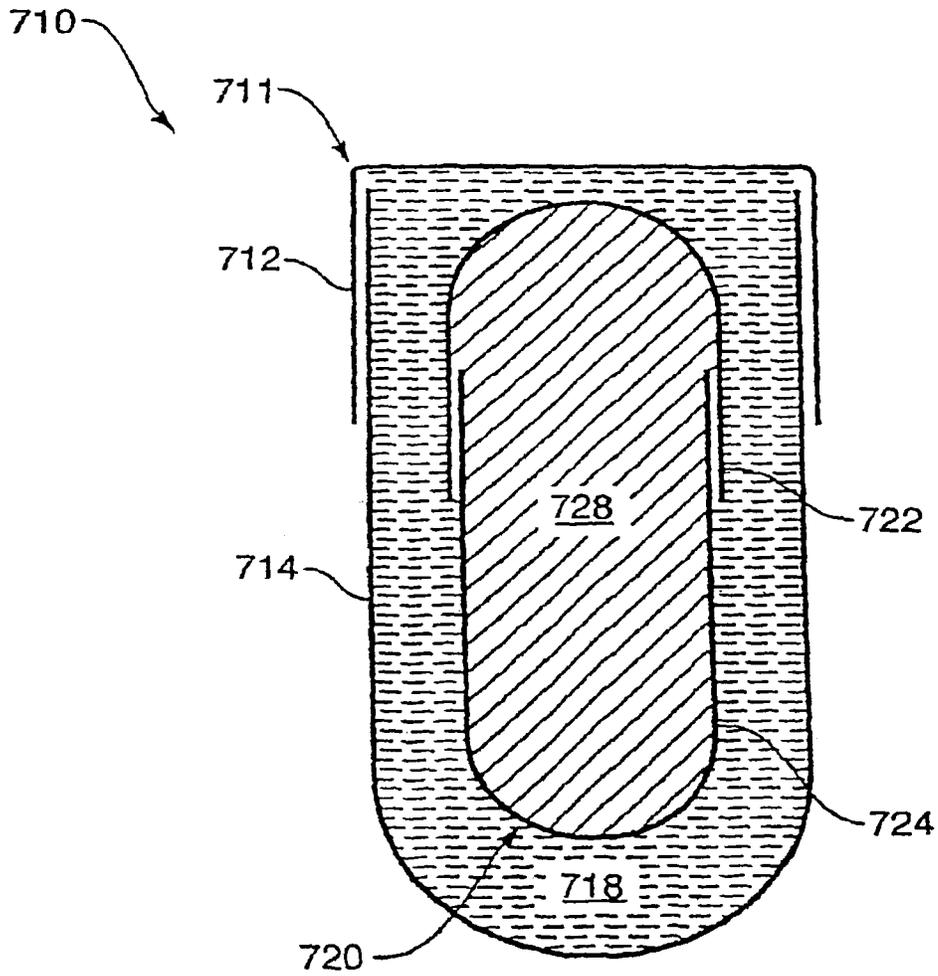


FIG. 10

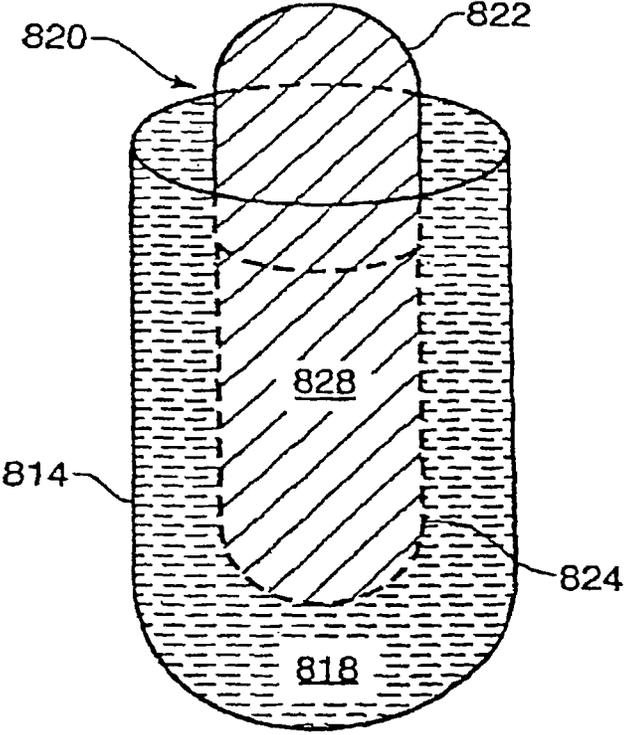
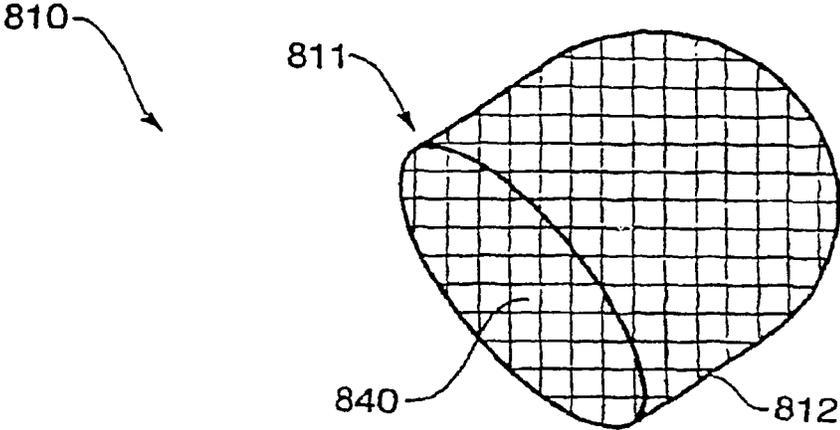


FIG. 11

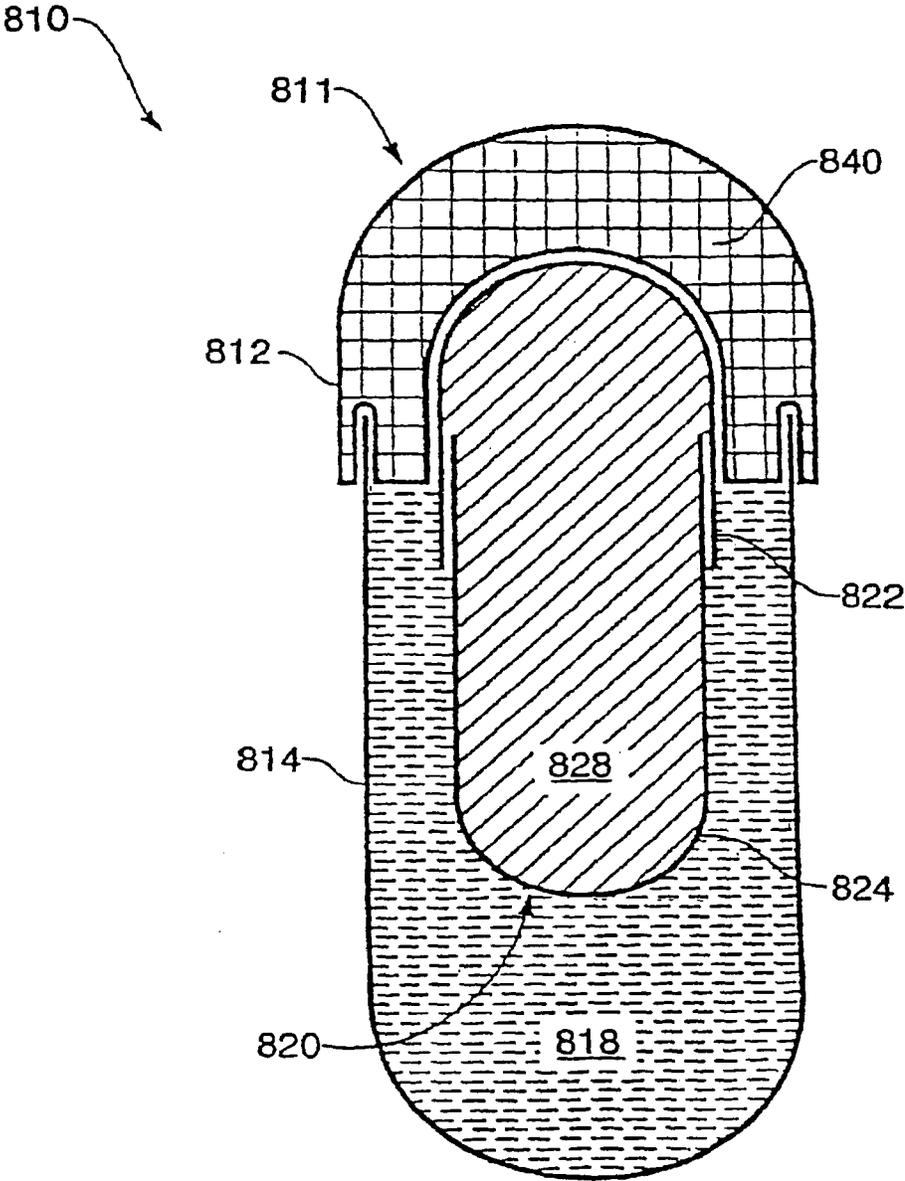


FIG. 12

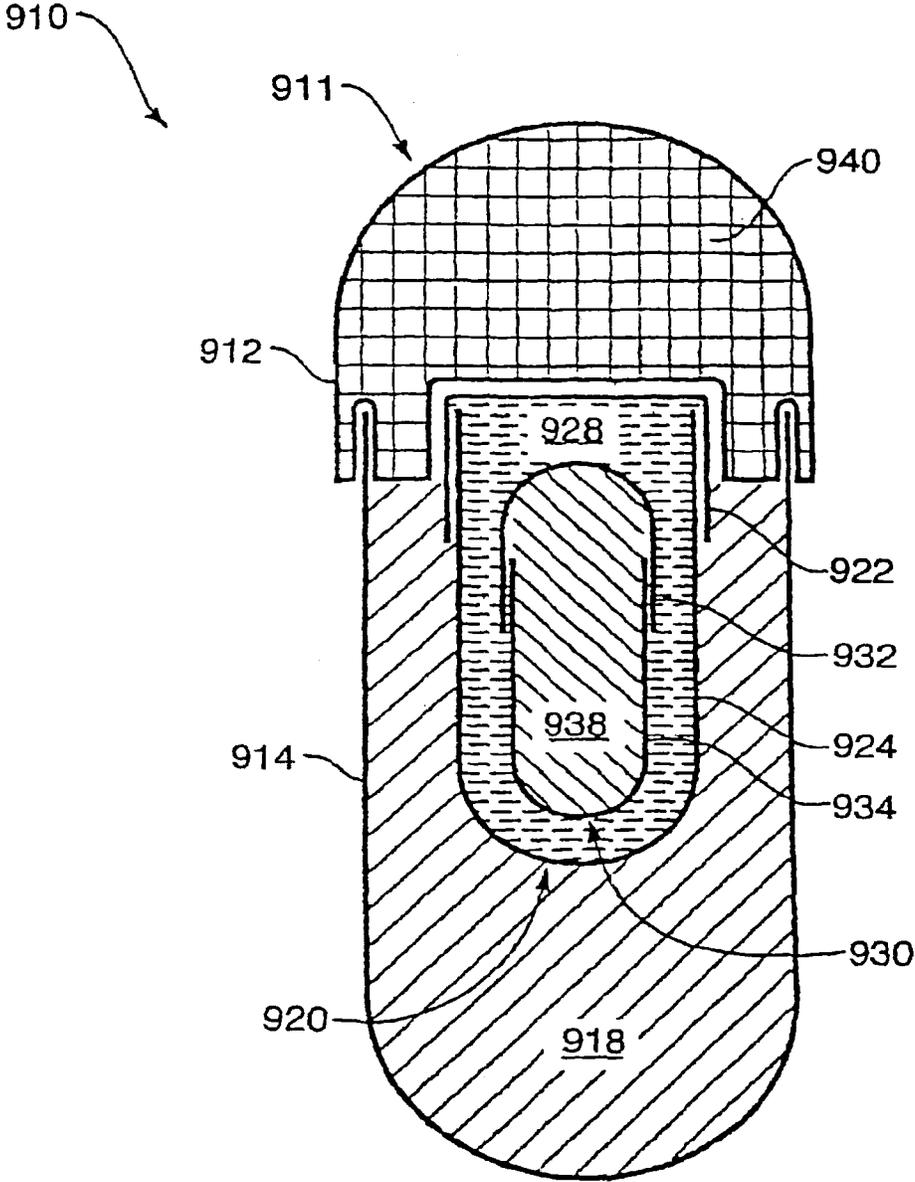


FIG. 13

1

**MULTI-PHASE, MULTI-COMPARTMENT,  
CAPSULAR DELIVERY APPARATUS AND  
METHODS FOR USING SAME**

RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 10/804,576, filed Mar. 19, 2004, and entitled "MULTI-COMPARTMENT CAPSULAR DELIVERY APPARATUS AND METHODS FOR USING THE SAME", which is a continuation-in-part of PCT/US/03/10816 filed Apr. 9, 2003, and entitled "MULTI-PHASE, MULTI-COMPARTMENT CAPSULAR SYSTEM", the contents of which are hereby incorporated by reference in their entirety. This application incorporates herein by reference U.S. Provisional Application Ser. No. 60/371,448, filed Apr. 10, 2002, and entitled "INTEGRATED CAPSULE DELIVERY APPARATUS AND METHOD." This application further claims the benefit of U.S. application Ser. No. 10/369,427, filed Feb. 18, 2003, entitled "MULTI-PHASE, MULTI-COMPARTMENT CAPSULAR DELIVERY APPARATUS AND METHODS FOR USING SAME," which is hereby incorporated herein by reference. This application further claims the benefit of U.S. application Ser. No. 10/368,951, filed Feb. 18, 2003, entitled "PROCESS FOR ENCAPSULATING MULTI-PHASE, MULTI-COMPARTMENT CAPSULES," which is hereby incorporated herein by reference. This application further claims the benefit of U.S. application Ser. No. 10/369,244, filed on Feb. 18, 2003, and entitled "MULTI-PHASE, MULTI-COMPARTMENT CAPSULAR DELIVERY APPARATUS FOR THERAPEUTIC COMPOSITIONS AND METHODS FOR USING SAME," which is hereby incorporated herein by reference. This application further claims the benefit of U.S. application Ser. No. 10/369,247, filed Feb. 18, 2003, and entitled "PROCESS FOR ENCAPSULATING MULTI-PHASE, MULTI-COMPARTMENT CAPSULES FOR THERAPEUTIC COMPOSITIONS," which is hereby incorporated herein by reference.

BACKGROUND

1. The Field of the Invention

The present invention relates to delivery of active ingredients or medicaments and, more particularly, to novel capsular delivery apparatus and methods for delivering one or more active ingredients or medicaments having diverse physical states (e.g., solid, liquid, gas or dispersion) into a single dosage, multi-compartment capsule.

The present invention further relates to methods for the administration of a plurality of heterogenous chemical and biological compounds to animals and humans using a multi-compartment delivery system for treatment of different conditions or the same condition or diseases (different or same) in one or more organ systems.

2. Background of the Invention

As appreciated by those skilled in the art, the contemplation, design, testing and manufacture of chemicals and biomolecules for administration to humans and animals, as nutritional or therapeutic agents, requires a thorough integration of clinically contemplated delivery principles and modalities. Chemicals and biomolecules that may be administered to humans and animals are often referred to herein as "actives," "active ingredients" or "medicaments."

Oral administration has become one of the most frequent routes for delivering one or more active ingredients or medicaments to the body. Active ingredients or medicaments, such as nutritional or therapeutic agents, may be orally adminis-

2

tered in a variety of physical states (i.e., solid, liquid or gas). Tablets and capsules are generally the most common vehicle for the oral delivery of medicaments. As appreciated, a tablet may be broadly characterized as a compressed powder or granular solid. Prior to compression of the granular powder comprising the medicament into tablet form, the presence of one or more excipients may be required. An excipient includes any inert substance (i.e., gum arabic, starch or the like) combined with a principal ingredient to facilitate the preparation of an agreeable or convenient dosage form of the active or medicament. Functional characteristics of excipients may include, for example, disintegration, lubrication, appearance, palatability, shelf-stability or the like.

Those skilled in the art also developed capsules as a contrivance for containing a solid or liquid dosage form of a medicament. Traditional capsular embodiments include a first containment section referred to as a base, and a second containment section referred to as a cap. The two pieces of the capsule are usually formulated and designed in a manner such that the material to be encapsulated may be introduced into the base section, whereas the open end of the cap section may be correspondingly positioned over the open end of the base. The walls of the cap and base are generally in physical contact with one another to form a single internal cavity. A means for structurally sealing the cap in relation to the base may also be incorporated during manufacture to insure non-tampering of the capsule. In this regard, those skilled in the art developed sealing technology which contemplates banding, heat fusion (spot-welding) and snap seals which utilize a "tongue and groove" scheme.

The outer walls of a capsule are preferably formed of a soluble ingredient, such as, for example, gelatin (animal-based product), starch, hydrophillic polymer or hydroxypropyl methyl-cellulose (HPMC), which provides a barrier for containing the active ingredient or medicament, in powder or liquid form, within the internal periphery of the capsule walls. Traditionally, hard gelatin capsules may be manufactured by dipping plates of stainless steel pins into a pool of gelatin solution. The pins are then removed from the gelatin and rotated while the gelatin is dried in a kiln with forced, humidity-controlled air. Once dried, the gelatin capsules are typically stripped from the pins, trimmed to a suitable length and then joined together (e.g. base and cap) and packaged for production use.

With the advent of automated encapsulation machinery, the responsibility to produce encapsulated products shifted mainly to industrial manufacturers. Contemporaneous with the development of the encapsulation industry, those skilled in the art have advanced the state of the encapsulation art. For example, several significant improvements in encapsulation technology have been seen over the last forty years. These technological improvements have included, for example, the development of soft elastic capsules, film-coating techniques, micro-encapsulation and multiple-compartment technology.

Soft elastic capsules, often referred to as soft gelatin capsules, were developed in an effort to provide means for encapsulating liquids and other medicaments which are typically poorly soluble in water. In preferred design, soft elastic capsules are made from a thicker and more plastic gelatin having an increased flexibility due to the addition of a polyol, such as glycerin or sorbitol. The addition of such plasticizers has been found, however, to have the potential disadvantage of increasing the risk for microbial growth. Thus an antimicrobial, such as a paraben or sorbic acid, may be added to the soft elastic capsule shell in order to address any microbial concern.

Prior art film-coating techniques generally involve a plating process, whereby a thin, uniform film may be deposited

onto the outer surface of the of the delivery vehicle (e.g., tablet or capsule). Several successive layers may be deposited onto the outer surface of the vehicle, if desired, in an effort to facilitate various desirable properties. For example, sugar-coating, a precursor to film-coating, has been used by those skilled in the art for more than one hundred years to make tablets more palatable. Other advantages or properties of film-coating may include for example, but not by way of limitation, protection from moisture, oxidation, controlling microbial contamination and inhibiting modification of the chemical properties of the active ingredient. As further appreciated by those skilled in the art, prior art film-coating may form an interfacial barrier between two chemicals or chemical compounds that might otherwise react when they come into contact.

Enteric coatings and sustained-release formulations are contemplated as variations on prior art film-coating techniques. In particular, enteric coating describes a process where the delivery vehicle (e.g., tablet or capsule) is coated with one or more layers of chemicals that are somewhat resistant to extreme pH conditions. For example, conditions of extremely low pH are commonly encountered in the stomach. Many active ingredients or medicaments are in the form of a pharmaceutical salt and thus highly susceptible to ionization in the presence of hydrogen ions. Thus, the presence of an enteric coating generally provides a level of protection as to degradation of the active ingredient or medicament until transit from the stomach into the small intestine is accomplished.

Film coatings have also led to the development of delivery vehicles (e.g., tablets and capsules) having sustained-release properties. Mixtures of waxes, cellulose, silicone and similar resins have been found useful by those skilled in the art for creating-sustained release coatings. In principle, these prior art coatings function to delay the release of the active ingredient or medicament to the targeted body system, thereby facilitating a timed, absorption rate in the body. Furthermore, the entire daily dosage of an active or medicament may be contained in a single, sustained-release delivery vehicle (e.g., tablet or capsule), whereas the immediate absorption of the entire dosage could possibly lead to an overdosage of the medicament. Thus, by layering quanta of medicament with differential coatings, the dosage undergoes a controlled release over specified time period. The application of sustained-release film coating technology therefore may inherently facilitate the delivery of a total daily dosage amount of an active or medicament to be released to the body in controlled increments.

Over the last several years, a considerable amount of attention has been focused on the further development of multi-compartment capsule technology for the delivery of therapeutic and diagnostic agents. Series formulations teach the use of membranes or other types of barriers to cordon a line of separate chambers within a single encapsulating shell. As appreciated, the purpose of such multi-compartment delivery devices is the administration of multiple dosages. Moreover, multiple-compartment delivery mechanisms of the prior art were developed to circumvent or diminish the effects of harsh pH environments within humans. For example, the prior art contemplates a hard capsule formulation which contains three different compartments of active medicaments for administration to the vaginal and rectal areas. In preferred structure, the formulation outer, rapid-release layer may contain an active medicament and excipient; the middle, intermediate-release layer may include a powder form of active medicament; and the inner, slow-release layer may contain pellets or granules of active medicament.

Also taught in the prior art are multi-compartment capsules having groups of spheroids with pH-dependent coatings which are encapsulated within a hard gelatin shell and provided for treating female yeast infection. The first spheroid is preferably uncoated and may be in a powder form; the second spheroid may contain a pH sensitive coat; and the inner spheroid may include a pH insensitive coat.

In addition to pH-sensitive coatings, hydrogels and other gastric retention technologies have been developed by those skilled in the art in an effort to retard the progression of the delivery vehicle during enteric transit. This retarding action, presumably, allows the full amount of active medicament to be released and/or targeted to a specific area of the gastrointestinal tract. Hydrogel and related gastric retention devices of the prior art generally rely upon the imbibing of water into a center core which is filled with cellulose or similar water absorbent material. In preferred operation, the material swells and releases multiple compartments of active medicament. The concept of using bulk size to slow transit of single active medicament in a single physical state is thus appreciated.

In an effort to administer active ingredients or medicaments to a specific location in the body to treat a specific disorder caused by a specific pathogen, those skilled in the art have used targeted-release systems using multi-compartment capsular technology. For example, a method for carrying out a triple therapy against the microorganisms *Helicobacter pylori*, a known infectious agent which is believed largely responsible for the development of gastric ulcer disease, was developed which comprises the steps of oral administration of a pharmaceutical dosage form comprising an internal capsule placed inside an external capsule, wherein the external capsule comprises a soluble salt of bismuth and a first antibiotic, and the internal capsule comprises a second antibiotic. In addition, multi-compartmental capsules were developed which combine, a nutrient supplement with a viable directed microbial (i.e., gastrointestinal microorganisms, including bacteria, live cell yeasts, fungi or a combination thereof) for the purpose of treating livestock for feeding disorders and improving feed efficiency.

A disadvantage with prior art encapsulation technology is when the base and corresponding cap of a capsule are joined, dead space volume is typically created within the internal periphery of the capsule. Internal capsular dead space may be filled with an air bubble which may ultimately react with one or more of the active ingredients or medicaments introduced within the capsule, thereby potentially degrading the quality and effectiveness of the active ingredients.

Although the prior art discloses multiple compartment, capsular delivery technology, these manifestations generally includes one of two approaches. For example, one approach contemplates the introduction of a single active or medicament into multiple capsular compartments to vary the temporal release of the medicament and ultimately the absorption rate into the body. Another approach contemplates the introduction of a plurality of active ingredients or medicaments into different compartments of a single capsule for delivery to a specific area of the body to treat a targeted illness or condition.

The use or contemplation of multiple-compartment capsular delivery apparatus or methods which deliver different physical forms of the same active or medicament, or a variation in physical forms of different actives or medicaments in a single dosage, however, has not heretofore been contemplated in the art. As appreciated by those skilled in the art, active ingredients or medicaments may take the physical form of a solid (e.g., pill, tablet, capsule (both hard and soft elastic),

powder, granulation, flakes, troches (lozenges and pastilles), suppositories and semi-solid ointments, pastes, emulsions and creams), a liquid (e.g., solution, spirits, elixir, syrups, sprays and fluid extracts), a gas or a dispersion. A dispersion is a system in which a dispersed phase is distributed through a continuous phase (e.g., aerosols (liquid or solid in gas), suspensions (solid in liquid), emulsion (liquid in liquid), foam (gas in liquid), solid foam (solid in gas) or gel (liquid or solid in solid)). Dispersions can be classified as molecular, colloidal and coarse, depending on size. In many circumstances, however, the different physical forms or phases of more than one active ingredient or medicament may not be suitably combined or mixed together without altering the individual desirable properties of the active ingredient or medicament. For example, although it would be possible and desirable to formulate a dispersion by combining a first active ingredient in the solid state with a second active ingredient that exists as a liquid, adverse chemical interactions between the active ingredients may adversely affect various characteristics of the ingredients, including but not limited to, their shelf lives. The resulting chemical decomposition—and the potential formation of any unwanted side products—could result in diminished drug potency or even toxicity to a patient.

Additionally, the physical properties of crystalline active ingredients could be drastically altered in scenarios where it is desirable to co-administer a crystalline active ingredient with a liquid or semi-liquid different active ingredient. In this context, the control of physical properties such as active ingredient dissolution rate and solubility is often a critical factor in determining the overall bioavailability of the active ingredient. It is well established in the art that different polymorphs or solvates of the same crystalline active ingredient exhibit dramatically different solubility and dissolution rates. Thus, combining a crystalline active agent with a liquid or semi-liquid active agent could give rise to an equilibrium between concentrations of different polymorphs and/or solvates of the crystalline active ingredient, and thereby frustrate efforts at tailoring an active ingredient mixture to its intended purpose as a medicament.

Another shortcoming with co-administering plural active ingredients in different physical forms in an intimate mixture is the potential for adverse in vivo drug-drug interactions upon administration. The desire to co-administer these active ingredients would be offset by the one active ingredient, for example as in a liquid or semi-liquid (e.g., a paste, solution, or syrup) form, becoming rapidly available. In this context, the active ingredient may adversely react with a co-administered drug, for example a less bioavailable solid or semi-solid, in a physiological environment. Thus, the true therapeutic benefit resulting from the pharmacological effects of the individual active agents may never be realized. It would be desirable to co-administer plural active ingredients while insuring against the potential of such harmful drug-drug interactions.

Providing active ingredients or medicaments in separate capsules may also be undesirable in the context of patient compliance. Geriatric and pediatric populations in particular disfavor the handling and consumption of multiple capsules of active ingredients. Patient compliance is essential in maintaining patient health in many dosage regimens. For example, deviations from accurate dosing and consistent consumption of immunosuppressant therapies can result in severe or even lethal consequences for a patient. Providing combined dosages of active ingredients would result in fewer capsules a patient or consumer would have to take, and thereby contribute to an overall increase in compliance.

Therefore, it would be desirable to provide a multi-compartment capsular delivery apparatus and methods that pro-

vide active ingredients or medicaments having diverse physical properties (e.g., solid, liquid, gas or dispersion), which may not be properly combined or stored together into a unitary structure (i.e., multi-compartment capsule) for usage in a single dosage form. The present invention, in overcoming the shortcomings of the prior art, satisfies these and other objectives.

The art and practice of pharmacy can be divided into four distinct divisions. Pharmacology is the study of interactions occurring between the pharmacologic agent, or medicament and specific targeted cells in the body. More specifically, the interaction between an active agent and a cellular receptor along with the resulting change in cell physiology is examined. Medicinal chemistry is largely concerned with the identification of naturally occurring and synthetic compounds which possess medicinal characteristics.

Pharmacotherapeutics is the holistic application of pharmacy practice to specific pathologies, illnesses, and other body functions. Finally, Pharmaceutical science ascertains or regulates the composition of medicinal substances, and is largely directed to the development of new mechanisms for delivering chemicals and biomolecules into animals and humans. A subcategory of pharmaceutical science is called pharmacokinetics and sometimes generally referred to as biopharmaceutics.

A.D.M.E. is an acronym often used to describe the four essential components to pharmaceutical science: absorption, distribution, metabolism, and elimination, respectively. One way to differentiate between pharmacology and pharmaceutical science is that the former is primarily concerned with the effect of the medicament on the body, whereas, the latter is primarily concerned with the delivery and time-course of the medicament on its journey through the body.

In clinical applications, chemicals and biomolecules are often referred to as active ingredients or medicaments. Medicaments may include “pharmaceuticals, nutraceuticals, biotechnicals, vitamins, minerals and dietary supplements.” Oral administration is the most frequent route for delivery of medicaments. Medicaments may be orally administered in a variety of physical states, including, solid, liquid, dispersion, and gaseous forms. As appreciated, tablets and capsules are the most common vehicle for oral delivery of medicaments.

Frequently, a medical or surgical patient may receive a plurality of concurrent medicaments. Data has been accumulated to demonstrate that patients undergoing a surgical procedure may receive ten (10) or more medicaments during the surgery and the resulting surgical recovery period. Some patients who have undergone organ transplantation or who have contracted human immunodeficiency virus (HIV) may receive three (3) or more medicaments which require multiple administrations per day. HIV patients often receive many more than three (3) medicaments. These medicaments may be necessary for the treatment of several conditions occurring in a plurality of organ systems or they may be necessary to treat a single condition or some combination thereof.

In some cases, it may be desirable to combine a plurality of medicaments because of a synergistic interaction between a plurality of medicaments. This synergy may enhance the efficacy of one or more of the medicaments. Medicaments may be combined to increase the intensity of response or efficacy. A plurality of medicaments, in combination, may be homergic (i.e., elicit the same quality of effect). In many cases, a plurality of homergic medicaments may also be homodynamic (i.e., interact with the same receptor). A plurality of homergic medicaments may be additive, supra-additive and infra-additive. A plurality of combined medicaments which do not produce the same quality of response may be called,

heterergic. When heterergy is found to be a positive effect (i.e., at least one medicament enhances the response to another medicament), this may be called synergism and is sometimes called synergy.

In further cases, it may be desirous to combine a plurality of medicaments to decrease their individual dosages and possibility for toxicity. It may also be desirous to combine a plurality of medicaments to target the treatment of a disease, illness or condition from divergent angles. It may be desirous to combine a plurality of medicaments to minimize the side effects and adverse effects of one or more medicaments. It may be still further desirous to combine a plurality of medicaments to alter the pharmacokinetic characteristics of one or more medicaments. For example, alterations in the absorption, distribution, metabolism or elimination of one or more medicaments.

Fixed combinations of a plurality of medicaments have been generally disfavored due to any number of perceived disadvantages. These disadvantages may include, for example: (1) complicating the interpretation of safety and efficacy in therapeutic regimens, (2) there may be inter-patient differences to fixed combinations, (3) there may be difficulties in dosage titration, and (4) the delivery platforms for fixed combinations have generally been found to be uneconomical to produce.

On the other hand, fixed combinations of a plurality of medicaments may lead to several therapeutic advantages, including, for example, but not by way of limitation: (1) increasing patient compliance with therapy, (2) increasing efficacy by optimizing timing of medicaments, (3) minimization of side effects and adverse effects, (4) enhancement of pharmacokinetic characteristics of one or more medicaments in a fixed combination, (5) increased patient quality of life, (6) optimization of institutional resources by minimizing the amount of medicament administrations, and (7) minimizing patient length of stay in institutional facilities by optimizing therapy.

Prior art therapeutic technologies contain isolated examples of pharmaceutical formulations containing fixed combinations of medicaments. However, therapeutic technologies of the prior art teach a fixed combination, wherein a plurality of medicaments are placed into a single receiving chamber in the delivery formulation (i.e., no separation between the plurality of medicaments).

In view of the state of the technology as it exists today, generally, therapeutic apparatus and methods are needed to provide a plurality of medicaments for medical and surgical conditions, as well as maintenance of normal health function for delivery to animals and humans using a multi-chambered delivery apparatus. Such apparatus and methods for delivering a plurality of medicaments to animals and humans using a multi-chambered delivery apparatus are contemplated herein.

#### BRIEF SUMMARY AND OBJECTS OF THE INVENTION

In view of the foregoing, it is a primary object of the present invention to provide novel integrated capsule delivery apparatus and methods for delivering diverse physical states (e.g., solid, liquid, gas or dispersion) of a single active ingredient or medicament, or a plurality of active ingredients or medicaments, in a single dosage form, wherein at least two of the active ingredients or medicaments have physical states that differ.

It is also an object of the present invention to provide novel integrated capsule delivery apparatus and methods which

facilitate various desirable properties including, for example, controlling time-release of key active ingredients or medicaments, prolonging shelf-life of the active ingredients or medicaments, improving palatability, reducing overall production costs and, accordingly, reducing the number of capsules consumed by a patient or consumer as nutritional or therapeutic agents.

Further, it is an object of the present invention to provide novel integrated capsule delivery apparatus and methods for delivering one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) in the form of a single dosage, multi-compartment capsule having one or more active ingredients in a primary capsule, and one or more active ingredients introduced into a secondary smaller capsule having a size sufficient for being selectively positionable within the primary capsule, wherein the active ingredient(s) within the primary capsule comprises a physical state (e.g., solid, liquid, gas or dispersion) that is different from the physical state of the active ingredient(s) in the secondary capsule.

It is an additional object of the present invention to provide novel integrated capsule delivery apparatus and methods for delivering one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) in the form of a single dosage, multi-compartment capsule having one or more active ingredients in a primary capsule and the same active ingredient(s) introduced into a smaller secondary capsule having a size sufficient for being positionable within the primary capsule, wherein the active ingredient(s) in the primary capsule comprises a physical state (e.g., solid, liquid, gas or dispersion) different from the active ingredient(s) in the secondary capsule.

It is a further object of the present invention to provide novel integrated capsule delivery apparatus and methods for delivering one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) in the form of a single dosage, multi-compartment capsule wherein at least one of the primary and secondary capsules include a time-release coating for controlling the release of the active ingredient(s) contained therein.

It is also another object of the present invention to provide novel integrated capsule delivery apparatus and methods for delivering one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) in the form of a single dosage, multi-compartment capsule having one or more active ingredients in the capsular body, wherein the capsule includes a longitudinally extending body and at least one dividing wall formed along a length of the extending body to form a first chamber and an opposing second chamber within the capsular body and introducing at least one active ingredient or medicament having a first physical state into the first chamber and at least one active ingredient or medicament having a second physical state into a second chamber, whereas the physical state (e.g., solid, liquid, gas or dispersion) of the ingredient(s) in the first chamber is different from the physical state of the ingredient(s) in the second chamber.

It is an additional object of the present invention to provide novel integrated capsule delivery apparatus and methods for delivering one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) in the form of a single dosage, multi-compartment capsule having a longitudinally extending body and one or more dividing walls

disposed along the length of the longitudinally extending body of the capsule, wherein the capsule and one or more of the dividing walls contained therein may include time-release coatings for controlling the release of the active ingredients or medicaments contained therein, respectively.

It is a further object of the present invention to provide novel integrated capsule delivery apparatus and methods for delivering one or more active ingredients or medicaments (e.g. pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) in the form of a single dosage, multi-compartment capsule having a plurality of active ingredients or medicaments having the physical form of a solid (e.g. pill, tablet, capsule (both hard and soft elastic), powder, granulation, flakes, troches (lozenges and pastilles), suppositories and semi-solid ointments, pastes, emulsions and creams), a liquid (e.g., solution, spirits, elixir and fluid extracts), a gas or a dispersion (e.g., aerosols (liquid or solid in gas), suspensions (solid in liquid), emulsion (liquid in liquid), foam (gas in liquid), solid foam (solid in gas) or gel (liquid or solid in solid), wherein the physical form of the active ingredients differ between a primary and secondary capsule, and between one or more dividing walls disposed in spaced-apart relationship along the length of a longitudinally extending capsular body.

It is a still further object of the present invention to provide novel integrated capsule delivery apparatus and methods for delivering one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) in the form of a single dosage, multi-compartment capsule, wherein an encapsulation process comprises the steps of: (1) providing a capsule comprising a first end, a second end, a longitudinally extending body having a length disposed between the first and second ends, and a plurality of dividing walls spaced apart along the length of the extending body, wherein the dividing walls form a plurality of receiving chambers; (2) introducing at least one active ingredient having a first physical state into a first receiving chamber; (3) introducing at least one active ingredient having a second physical state into a second receiving chamber; (4) introducing at least one active ingredient having a third physical state into a third receiving chamber, wherein the physical states of at least two of the active ingredients introduced into the first, second or third receiving chambers differ; and (5) sealing the first and second ends of said capsule.

Additionally, it is an object of the present invention to provide novel integrated capsule delivery apparatus and methods for delivering a single dosage, multi-compartment capsule comprising a capsular base and cap configuration, wherein the size and shape of the cap, relative to its sealing relationship with the base, generally eliminates or substantially reduces any potential dead space volume within the internal periphery of the capsule, thereby functionally negating the opportunity for reaction between an air bubble and one or more active ingredients introduced into the capsule and, accordingly, improving stability of the capsular ingredient(s).

Consistent with the foregoing objects, and in accordance with the invention as embodied and broadly described herein, one presently preferred embodiment of the novel integrated capsule delivery apparatus and methods of the present invention comprises a multi-compartment capsule including a primary capsule and a secondary capsule selectively positionable within an internal periphery of the primary capsule. The secondary capsule may include a base, a corresponding cap and one or more receiving chambers. Each of the receiving chambers of the secondary capsule may be formed having an internal periphery sufficient for receiving at least one active

ingredient or medicament (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) therein. Similarly, the primary capsule may be formed having a base, a corresponding cap and one or more receiving chambers. The receiving chambers of the primary capsule may be formed having an internal periphery sufficient for receiving the secondary capsule and one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) having a physical state (i.e., solid, liquid, gas or dispersion) different from the physical state of the active ingredient(s) housed within the receiving chamber of the secondary capsule.

As further contemplated herein, a multi-compartment capsule is provided comprising a base, a corresponding cap and one or more dividing walls positionable between the base and the cap. Structurally, the size, shape and positioning of the dividing walls relative to the base and corresponding cap facilitates the formation of at least two, independent and separate receiving chambers. Each of the receiving chambers having an internal periphery sufficient for receiving one or more active ingredients or medicaments (e.g. pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) therein. In preferred design, the physical state (e.g., solid, liquid, gas or dispersion) of the active ingredient(s) in the first receiving chamber is different from the physical state of the active ingredient(s) in the second receiving chamber. After introducing one or more active ingredients or medicaments into each receiving chamber, the cap may be selectively positioned in sealing relationship with the base to form one presently preferred embodiment of the single, dosage multi-compartment capsule.

One presently preferred embodiment of an encapsulation process for forming a multi-compartment capsule may comprise the steps of: (1) providing a primary capsule having a base, a corresponding cap and a receiving chamber; (2) providing a secondary capsule having a base, a corresponding cap and a receiving chamber; (3) introducing at least one ingredient or medicament (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) having a first physical state (e.g., solid, liquid, gas or dispersion) into at least a portion of the receiving chamber of the secondary capsule and selectively positioning the cap in sealing relationship with the base; (4) introducing at least one ingredient or medicament (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) having a second physical state (e.g., solid, liquid, gas or dispersion) into at least a portion of the receiving chamber of the primary capsule, wherein the first physical state of the ingredient(s) in the secondary capsule is different from the second physical state of the ingredient(s) in the primary capsule; and (5) introducing the secondary capsule into at least a portion of the receiving chamber of the primary capsule and selectively positioning the cap in sealing relationship with the base to form a single dosage multi-compartment capsule.

In alternate presently preferred embodiments of the present invention, a tertiary capsule comprising a base, a corresponding cap and a receiving chamber having an internal periphery sufficient for receiving one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) may be selectively introduced within an internal periphery of at least one receiving chamber of the secondary capsule. After the introduction of at least one active ingredient into one or more receiving chambers of a tertiary capsule pursuant to an encapsulation process of the present invention,

the cap of the tertiary capsule may be selectively positioned in sealing relationship with the base and then introduced into at least a portion of the internal periphery of the secondary capsule, together with one or more active ingredients therein. It is contemplated herein that at least two of the active ingredients introduced within the receiving chambers of the primary, secondary and tertiary capsules, respectively, comprise at least two different physical states (e.g., solid, liquid, gas or dispersion).

In preferred structural design, the primary capsule may comprise a cap having a generally U-shaped configuration adapted to provide a sealing relationship when engaging the corresponding base, thereby reducing dead space volume in the internal periphery of the cap and receiving chamber of the base. A cap having a configuration adapted to generally eliminate or substantially reduce potential dead space volume of the cap and receiving chamber of the base may, accordingly, function—to negate the potential for a reaction between an air bubble and one or more active ingredient(s) introduced into the base of the primary capsule.

Alternatively, a multi-compartment capsule of the present invention may include the introduction of a filling material into the cap of the primary capsule, the cap having a general cylindrical configuration adapted to provide a sealing relationship when engaging the corresponding base. An amount of filling material may be introduced into at least a portion of the internal periphery of the cap to fill, either partially or completely, the inner volume of the cap, thereby reducing the dead space volume in the cap and the internal periphery of the receiving chamber of the base. In this regard, the introduction of a filling material relative to the internal periphery of the cap may generally eliminate or substantially reduce the potential dead space volume, thus functionally negating the potential for a reaction between an air bubble and one or more active ingredient(s) introduced into the base of the primary capsule.

The primary, secondary or tertiary capsules, in accordance with the present invention, may be formed having the same or different colors. Moreover, the base and corresponding cap of a single capsule may be formed having different colors in an effort to enhance the aesthetics of the capsule to the consumer. In one presently preferred embodiment of a multi-compartment capsule of the present invention, the dosage may be banded, sealed or easily dividable in a contact area of the primary and secondary capsules or the sealing band may be color-coded to assist in branding, if desired.

It is further contemplated herein that a multi-compartment capsule of the present invention may comprise component parts of the capsule having various time-release coatings to facilitate the release and ultimately the absorption of those active ingredients introduced into the different receiving chambers of the multi-compartment capsule to release at different release rates. In particular, a primary capsule may be formed having a conventional time-release coating that dissolves and releases the active ingredient(s) contained therein before the timed-release of the active ingredient(s) contained within a secondary capsule. Likewise, the dividing walls disposed within the internal periphery of the base of a capsule may be formed having conventional time-release coatings that dissolve and release the active ingredients within each receiving chamber defined by the dividing walls at different rates, thereby delivering the active ingredients or medicaments contained within a multi-compartment capsule at different rates. Certain active ingredients or medicaments may, therefore, be delivered at a selected interval, while other ingredients may be released at a later interval. In this way, the novel design of the multi-compartment capsules of the

present invention may facilitate precision delivery of active ingredients to targeted areas of the consumer.

Still further, a primary object of the present invention is to provide novel delivery apparatus and methods for affecting multiple organ systems in animals or humans using a plurality of medicaments delivered by a pharmaceutical formulation comprising a multi-chambered apparatus. Accordingly, the present invention provides novel delivery apparatus and administration techniques or methods aimed at affecting multiple organ systems in an animal or human using a plurality of medicaments. A delivery apparatus may be in any multi-chambered apparatus, but preferably in a capsular formulation. Thus, a plurality of medicaments may be encapsulated and stored separately within a larger capsule until the time of ingestion, consumption, or the like. Upon consumption, the capsule walls of one or more dividing walls of a capsule may dissolve to release their contents. Different methods of encapsulation may be used to deliver their respective contents, including but not limited to, dissolution, melting, ablation or biodegradation of the encapsulating wall. In certain embodiments and as contemplated herein, the medicaments retained in the multicompartiment capsule may actually diffuse through one or more of the encapsulating walls.

In one embodiment of the present invention there is a multi-compartment capsule, comprising a first receiving chamber comprising at least one ingredient having a first physical state, wherein said ingredient is selected from the group consisting of a nutraceutical, a vitamin, a dietary supplement and a mineral; and a second receiving chamber comprising at least one ingredient having a second physical state, wherein said ingredient is selected from the group consisting of a nutraceutical, a vitamin, a dietary supplement and a mineral; said first physical state of said ingredient of said first receiving chamber being different from said second physical state of said ingredient of said second receiving chamber.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, further comprising a base and a corresponding cap, wherein said cap is configured to provide a sealing relationship when engaging said base.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said cap comprises a configuration adapted to reduce dead volume space within said first receiving chamber.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, further comprising a filling material introduced into said cap to reduce dead volume space within said first receiving chamber.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said filling material is selected from the group consisting of gelatin, starch, casein, chitosan, soya bean protein, safflower protein, alginates, gellan gum, carrageenan, xanthan gum, phthalated gelatin, succinated gelatin, cellulosephthalate-acetate, polyvinylacetate, hydroxypropyl methyl cellulose, oleoresin, polyvinylacetate-phthalate, polymerisates of acrylic or methacrylic esters and combinations thereof.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said first receiving chamber comprises no dead volume space.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said physical state of said ingredient in said first receiving chamber is selected from the group consisting of a solid, a liquid, a gas and a dispersion.

13

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said physical state of said ingredient in said second receiving chamber is selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said solid is selected from the group consisting of a pill, a tablet, a capsule, a powder, granulation, flakes, a troche, a suppository, an ointment, a paste, an emulsion and a cream.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said liquid is selected from the group consisting of a solution, a spirit, an elixir, a spray, a syrup and a fluid extract.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said dispersion is selected from the group consisting of an aerosol, a suspension, an emulsion, a foam, a solid foam and a gel.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said first receiving chamber comprises a time-release coating.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said second receiving chamber comprises a time-release coating.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said time-release coating of said second receiving chamber is different from said time-release coating of said primary capsule.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, further comprising a third receiving chamber comprising at least one ingredient.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said ingredient in said third receiving chamber is selected from the group consisting of a nutraceutical, a vitamin, a dietary supplement and a mineral.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said ingredient in said third receiving chamber comprises a physical state selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said third receiving chamber comprises a time-release coating.

In another embodiment of the present invention, there is a multi-compartment capsule, comprising a primary capsule comprising at least one ingredient having a first physical state, wherein said ingredient is selected from the group consisting of a nutraceutical, a vitamin, a dietary supplement and a mineral; a secondary capsule comprising at least one ingredient having a second physical state, wherein said ingredient is selected from the group consisting of a nutraceutical, a vitamin, a dietary supplement and a mineral; said first physical state of said ingredient of said primary capsule being different from said second physical state of said ingredient of said secondary capsule; and said primary capsule comprising an internal periphery sufficient for receiving said ingredient and said secondary capsule therein.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said primary capsule further comprises a base and a corresponding cap, wherein said cap is configured to provide a sealing relationship when engaging said base.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said primary capsule comprises no dead volume space.

14

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said first physical state of said ingredient in said primary capsule is selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said second physical state of said ingredient in said secondary capsule is selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said primary capsule comprises a time-release coating.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said secondary capsule comprises a time-release coating.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said time-release coating of said secondary capsule is different from said time-release coating of said primary capsule.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said third receiving chamber comprises a time-release coating.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said primary capsule is formed of a material selected from the group consisting of gelatin, starch, casein, chitosan, soya bean protein, safflower protein, alginates, gellan gum, carrageenan, xanthan gum, phtalated gelatin, succinated gelatin, cellulosephtalate-acetate, oleoresin, polyvinylacetate, hydroxypropyl methyl cellulose, polymerisates of acrylic or methacrylic esters, polyvinylacetate-phtalate and combinations thereof.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said primary capsule further comprises a soft elastic capsule formed of a material selected from the group consisting of glycerin and sorbitol.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said soft elastic capsule includes an antimicrobial selected from the group consisting of paraben and sorbic acid.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said secondary capsule is formed of a material selected from the group consisting of gelatin, starch, casein, chitosan, soya bean protein, safflower protein, alginates, gellan gum, carrageenan, xanthan gum, phtalated gelatin, succinated gelatin, cellulosephtalate-acetate, oleoresin, polyvinylacetate, hydroxypropyl methyl cellulose, polymerisates of acrylic or methacrylic esters, polyvinylacetate-phtalate and combinations thereof.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said ingredient introduced in said primary capsule comprises a moisture content in the range of about 0% to 6% by weight.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said ingredient introduced in said secondary capsule comprises a moisture content in the range of about 0% to 6% by weight.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said primary and secondary capsules contain at least one pharmaceutically acceptable lubricant in the range of about 0% to 1.0% by weight.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said

15

lubricant is selected from the group consisting of aluminium-stearate, calciumstearate, magnesiumstearate, tinstearate, talc, sodium lauryl sulfate, lecithins, mineral oils, stearic acid, silicones and mixtures thereof.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said primary and secondary capsules have different colors.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said primary capsule is formed having a first color.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said secondary capsule is formed having a second color different from said first color of said primary capsule.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said capsule further comprises a base and a corresponding cap, wherein said cap is configured to provide a sealing relationship when engaging said base.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said base and said cap are formed having different colors.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said sealing relationship between said base and corresponding cap comprises no dead volume space.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said physical state of said ingredient in said first receiving chamber is selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said physical state of said ingredient in said second receiving chamber capsule is selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said capsule comprises a time-release coating.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said dividing wall comprises a time-release coating.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said time-release coating of said dividing wall is different from said time-release coating of said capsule.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said third receiving chamber comprises a time-release coating.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said capsule is formed of a material selected from the group consisting of gelatin, starch, casein, chitosan, soya bean protein, safflower protein, alginates, gellan gum, carrageenan, xanthan gum, phtalated gelatin, succinated gelatin, cellulosephthalate-acetate, oleoresin, polyvinylacetate, hydroxypropyl methyl cellulose, polymerisates of acrylic or methacrylic esters, polyvinylacetate-phtalate and combinations thereof.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said capsule further comprises a soft elastic capsule formed of a material selected from the group consisting of glycerin and sorbitol.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said dividing wall is formed of a material selected from the group consisting of gelatin, starch, casein, chitosan, soya bean pro-

16

tein, safflower protein, alginates, gellan gum, carrageenan, xanthan gum, phtalated gelatin, succinated gelatin, cellulosephthalate-acetate, oleoresin, polyvinylacetate, hydroxypropyl methyl cellulose, polymerisates of acrylic or methacrylic esters, polyvinylacetate-phtalate and combinations thereof.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said ingredient introduced in said first receiving chamber comprises a moisture content in the range of about 0% to 6% by weight.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said ingredient introduced in said second receiving chamber comprises a moisture content in the range of about 0% to 6% by weight.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said capsule contains at least one pharmaceutically acceptable lubricant in the range of about 0% to 10% by weight.

In another embodiment of the present invention there is, an encapsulation process for forming a multi-compartment capsule, said process comprising the steps of providing a primary capsule having a base and a cap; providing a secondary capsule having a base and a cap; introducing at least one ingredient having a first physical state into said secondary capsule, wherein said ingredient introduced into said primary, capsule is selected from the group consisting of a nutraceutical, a vitamin, a dietary supplement and a mineral; positioning said cap of said secondary capsule in sealing relationship with said base; introducing at least one ingredient having a second physical state into said primary capsule, wherein said ingredient introduced into said primary capsule is selected from the group consisting of a nutraceutical, a vitamin, a dietary supplement and a mineral; and wherein said first physical state of said ingredient of said secondary capsule is different from said second physical state of said ingredient of said primary capsule; introducing said secondary capsule into said base of said primary capsule; and positioning said cap of said primary capsule in sealing relationship with said base.

In another embodiment of the present invention there is, an encapsulation process as defined above, further comprising the step of reducing dead volume space within said primary capsule.

In another embodiment of the present invention, an encapsulation process as defined above, further comprising the step of introducing a filling material into said cap of said primary capsule to reduce dead volume space.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said filling material is selected from the group consisting of gelatin, starch, casein, chitosan, soya bean protein, safflower protein, alginates, gellan gum, carrageenan xanthan gum, phtalated gelatin, succinated gelatin, cellulosephthalate-acetate, polyvinylacetate, hydroxypropyl methyl cellulose, oleoresin, polyvinylacetate-phtalate, polymerisates of acrylic or methacrylic esters and combinations thereof.

In another embodiment of the present invention, an encapsulation process as defined above, wherein said cap of said primary capsule comprises a configuration sufficient for reducing dead volume space within the primary capsule.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said physical state of said ingredient in said primary capsule is selected from the group consisting of a solid, a liquid, a gas and a dispersion.

17

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said physical state of said ingredient in said secondary capsule is selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said ingredient introduced into said primary capsule is the same as said ingredient introduced into said secondary capsule.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said primary capsule comprises a time-release coating.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said secondary capsule comprises a time-release coating.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said time-release coating of said secondary capsule is different from said time-release coating of said primary capsule.

In another embodiment of the present invention, there is an encapsulation process as defined above, further comprising the steps of providing a tertiary capsule having a base and a cap; introducing at least one ingredient having a third physical state into said tertiary capsule; positioning said cap of said secondary capsule in sealing relationship with said base; and introducing said tertiary capsule into said base of said secondary capsule.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said ingredient in said tertiary capsule is selected from the group consisting of a nutraceutical, a vitamin, a dietary supplement and a mineral.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said ingredient in said tertiary capsule comprises a physical state selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said tertiary capsule comprises a time-release coating.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said primary capsule is formed of a material selected from the group consisting of gelatin, starch, casein, chitosan, soya bean protein, safflower protein, alginates, gellan gum, carrageenan, xanthan gum, phtalated gelatin, succinated gelatin, cellulosephthalate-acetate, polyvinylacetate, hydroxypropyl methyl cellulose, oleoresin, polymerisates of acrylic or methacrylic esters, polyvinylacetate-phtalate and combinations thereof.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said primary capsule further comprises—a soft elastic capsule formed of a material selected from the group consisting of glycerin and sorbitol.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said secondary capsule is formed of a material selected from the group consisting of gelatin, starch, casein, chitosan, soya bean protein, safflower protein, alginates, gellan gum, carrageenan, xanthan gum phtalated gelatin, succinated gelatin, cellulosephthalate-acetate, polyvinylacetate, hydroxypropyl methyl cellulose, oleoresin, polymerisates of acrylic or methacrylic esters, polyvinylacetate-phtalate and combinations thereof.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said second-

18

ary capsule further comprises a soft elastic capsule formed of a material selected from the group consisting of glycerin and sorbitol.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said ingredient introduced in said primary capsule comprises a moisture content in the range of about 0% to 6% by weight.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said ingredient introduced in said secondary capsule comprises a moisture content in the range of about 0% to 6% by weight.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said primary and secondary capsules contain at least one pharmaceutically acceptable lubricant in the range of about 0% to 10% by weight.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said lubricant is selected from the group consisting of aluminiumstearate, calciumstearate, magnesiumstearate, tinsteerate, talc, sodium lauryl sulfate, lecithins, mineral oils, stearic acid, silicones and combinations thereof.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said primary and secondary capsules are formed having different colors.

In another embodiment of the present invention, there is an encapsulation process for forming a multi-compartment capsule, said process comprising the steps of providing a capsule comprising a cap, a base configured having a longitudinally extending body including a length and at least one dividing wall formed along said length of said extending body, said dividing wall adapted to form a first receiving chamber and a second receiving chamber; introducing at least one ingredient having a first physical state into said second receiving chamber, wherein said ingredient introduced into said primary capsule is selected from the group consisting of a nutraceutical, a vitamin, a dietary supplement and a mineral; introducing at least one ingredient having a second physical state into said first receiving chamber, wherein said ingredient introduced into said primary capsule is selected from the group consisting of a nutraceutical, a vitamin, a dietary supplement and a mineral, and wherein said first physical state of said ingredient of said second receiving chamber being different from said second physical state of said ingredient of said first receiving chamber; and positioning said cap in sealing relationship with said base.

In another embodiment of the present invention, there is an encapsulation process as defined above, further comprising the step of reducing dead volume space within said primary capsule.

In another embodiment of the present invention, there is an encapsulation process as defined above, further comprising the step of introducing a filling material into said cap to reduce said dead volume space.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said filling material is selected from the group consisting of gelatin, starch, casein, chitosan, soya bean protein, safflower protein, alginates, gellan gum, carrageenan, xanthan gum, phtalated gelatin, succinated gelatin, cellulosephthalate-acetate, polyvinylacetate, hydroxypropyl methyl cellulose, oleoresin, polyvinylacetate-phtalate, polymerisates of acrylic or methacrylic esters and combinations thereof.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said cap comprises a configuration sufficient for reducing dead volume space within said capsule.

19

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said physical state of said ingredient in said receiving chamber is selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said physical state of said ingredient in said second receiving chamber is selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said first receiving chamber comprises a time-release coating.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said second receiving chamber comprises a time-release coating.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said time-release coating of said second receiving chamber is different from said time-release coating of said first receiving chamber.

In another embodiment of the present invention, there is an encapsulation process as defined above, further comprising the steps of positioning a second dividing wall along said length of said extending body, said second dividing wall adapted to form a third receiving chamber; and introducing at least one ingredient having a third physical state into said third receiving chamber.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said ingredient in said third receiving chamber is selected from the group consisting of a nutraceutical, a vitamin, a dietary supplement and a mineral.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said ingredient in said third receiving chamber comprises a physical state selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said dispersion is selected from the group consisting of an aerosol, a suspension, an emulsion, a foam, a solid foam and a gel.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said third receiving chamber comprises a time-release coating.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said capsule is formed of a material selected from the group consisting of gelatin, starch, casein, chitosan, soya bean protein, safflower protein, alginates, gellan gum, carrageenan, xanthan gum, phtalated gelatin, succinated gelatin, cellulosephthalate-acetate, polyvinylacetate, hydroxypropyl methyl cellulose, oleoresin, polymerisates of acrylic or methacrylic esters, polyvinylacetate-phtalate and combinations thereof.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said capsule further comprises a soft elastic capsule formed of a material selected from the group consisting of glycerin and sorbitol.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said primary and secondary capsules contain at least one pharmaceutically acceptable lubricant in the range of about 0% to 10% by weight.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said lubricant is selected from the group consisting of aluminiumstearate, calciumstearate, magnesiumstearate, tinstearate, talc,

20

sodium lauryl sulfate, lecithins, mineral oils, stearic acid, silicones and combinations thereof.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said base and said cap of said capsule are formed having different colors.

In another embodiment of the present invention, there is an encapsulation process as defined above, further comprising the step of introducing two or more dividing walls adapted to form a plurality of receiving chambers into said base of said capsule.

In another embodiment of the present invention, there is an encapsulation process as defined above, further comprising the step of introducing a capsule into one of said plurality of receiving chambers.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said capsule may comprise a multi-compartment capsule.

In another embodiment of the present invention, there is a multi-compartment capsule, comprising a first receiving chamber comprising at least one ingredient having a first physical state; and a second receiving chamber comprising at least one ingredient having a second physical state, wherein said first physical state of said ingredient of said first receiving chamber being different from said second physical state of said ingredient of said second receiving chamber.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said first receiving chamber comprises no dead space.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said cap is configured to reduce dead volume space within said first receiving chamber.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, further comprising a filling material introduced into said cap to reduce dead volume space within said first receiving chamber.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said ingredient in said first receiving chamber is selected from the group consisting of a pharmaceutical, a biotechnical, a nutraceutical, a vitamin, a dietary supplement and a mineral.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said ingredient in said second receiving chamber is selected from the group consisting of a pharmaceutical, a biotechnical, a nutraceutical, a vitamin, a dietary supplement and a mineral.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said ingredient in said first receiving chamber comprises a pharmaceutical and said ingredient in said second receiving chamber comprises a pharmaceutical.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said ingredient in said first receiving chamber comprises a pharmaceutical and said ingredient in said second receiving chamber is selected from the group consisting of a biotechnical, a nutraceutical, a vitamin, a dietary supplement and a mineral.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said physical state of said ingredient in said first receiving chamber is selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said

21

physical state of said ingredient in said second receiving chamber is selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said time-release coating of said second receiving chamber is different from said time-release coating of said primary capsule.

In another embodiment of the present invention, there is a multi-compartment capsule, comprising a primary capsule comprising at least one ingredient having a first physical state; a secondary capsule comprising at least one ingredient having a second physical state; said first physical state of said ingredient of said primary capsule being different from said second physical state of said ingredient of said secondary capsule; and said primary capsule comprising an internal periphery sufficient for receiving said ingredient and said secondary capsule therein.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said primary, capsule further comprises a base and a corresponding cap, wherein said cap is configured to provide a sealing relationship when engaging said base.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said primary capsule comprises no dead volume space.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said ingredient in said primary capsule is selected from the group consisting of a pharmaceutical, a biotechnical, a nutraceutical, a vitamin, a dietary supplement and a mineral.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said ingredient in said secondary capsule is selected from the group consisting of a pharmaceutical, a biotechnical, a nutraceutical, a vitamin, a dietary supplement and a mineral.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said ingredient in said first receiving chamber comprises a pharmaceutical and said ingredient in said second receiving chamber comprises a pharmaceutical.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said ingredient introduced in said primary capsule comprises a moisture content in the range of about 0% to 6% by weight.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said ingredient introduced in said secondary capsule comprises a moisture content in the range of about 0% to 6% by weight.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said primary and secondary capsules contain at least one pharmaceutically acceptable lubricant in the range of about 0% to 10% by weight.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said lubricant is selected from the group consisting of aluminium-stearate, calciumstearate, magnesiumstearate, tinstearate, talc, sodium lauryl sulfate, lecithins, mineral oils, stearic acid, silicones and mixtures thereof.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said primary and secondary capsules have different colors.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said primary capsule is formed having a first color.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said

22

secondary capsule is formed having a second color different from said first color of said primary capsule.

In another embodiment of the present invention, there is a multi-compartment capsule, comprising a capsule comprising a longitudinally extending body having a length; at least one dividing wall formed along said length of said extending body, said dividing wall forming a first receiving chamber and a second receiving chamber; said first receiving chamber comprising at least one ingredient having a first physical state; said second receiving chamber comprising at least one ingredient having a second physical state; and said first physical state of said ingredient of said first receiving chamber being different from said second physical state of said ingredient of said second receiving chamber.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said capsule further comprises a base and a corresponding cap, wherein said cap is configured to provide a sealing relationship when engaging said base.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said base and said cap are formed having different colors.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said sealing relationship between said base and corresponding cap comprises no dead volume space within said capsule.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said ingredient in said first receiving chamber comprises a pharmaceutical and said ingredient in said second receiving chamber comprises a pharmaceutical.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said ingredient in said first receiving chamber comprises a pharmaceutical and said ingredient in said second receiving chamber is selected from the group consisting of a biotechnical, a nutraceutical, a vitamin, a dietary supplement and a mineral.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said first physical state of said ingredient in said first receiving chamber is selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said second physical state of said ingredient in said second receiving chamber capsule is selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said capsule comprises a time-release coating.

In another embodiment of the present invention, there is a multi-compartment capsule as defined in above, wherein said capsule is formed of a material selected from the group consisting of gelatin, starch, casein, chitosan, soya bean protein, safflower protein, alginates, gellan gum, carageenan, xanthan gum, phtalated gelatin, succinated gelatin, cellulosephthalateacetate, polyvinylacetate, hydroxypropyl methyl cellulose, oleoresin, polymerisates of acrylic or methacrylic esters, polyvinylacetate-phtalate and mixtures thereof.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said capsule further comprises a soft elastic capsule formed of a material selected from the group consisting of glycerin and sorbitol.

In another embodiment of the present invention, there is a multi-compartment capsule as defined above, wherein said lubricant is selected from the group consisting of aluminium-

23

stearate, calciumstearate, magnesiumstearate, tinstearate, talc, sodium lauryl sulfate, lecithins, mineral oils, stearic acid, silicones and mixtures thereof.

In another embodiment of the present invention, there is an encapsulation process for forming a multi-compartment capsule, said process comprising the steps of providing a primary capsule having a base and a cap; providing a secondary capsule having a base and a cap; introducing at least one ingredient having a first physical state into said secondary capsule; positioning said cap of said secondary capsule in sealing relationship with said base; introducing at least one ingredient having a second physical state into said primary capsule, wherein said first physical state of said ingredient of said secondary capsule is different from said second physical state of said ingredient of said primary capsule; introducing said secondary capsule into said base of said primary capsule; and positioning said cap of said primary capsule in sealing relationship with said base.

In another embodiment of the present invention, there is an encapsulation process as defined above, further comprising the step of reducing dead volume space within said primary capsule.

In another embodiment of the present invention, there is an encapsulation process as defined above, further comprising the step of introducing a filling material into said cap of said primary capsule to reduce dead volume space.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said cap of said primary capsule comprises a configuration sufficient for reducing dead volume space within the primary capsule.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said ingredient introduced into said primary capsule is selected from the group consisting of a pharmaceutical, a biotechnical, a nutraceutical, a vitamin, a dietary supplement and a mineral.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said physical state of said ingredient in said primary capsule is selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said ingredient in said secondary capsule is selected from the group consisting of a pharmaceutical, a biotechnical, a nutraceutical, a vitamin, a dietary supplement and a mineral.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said physical state of said ingredient in said secondary capsule is selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said ingredient in said primary capsule comprises a pharmaceutical and said ingredient in said secondary capsule is selected from the group consisting of a pharmaceutical.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said ingredient in said primary capsule comprises a pharmaceutical and said ingredient in said secondary capsule is selected from the group consisting of a biotechnical, a nutraceutical, a vitamin, a dietary supplement and a mineral.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said ingredient introduced into said primary capsule is the same as said ingredient introduced into said secondary capsule.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said time-

24

release coating of said secondary capsule is different from said time-release coating of said primary capsule.

In another embodiment of the present invention, there is an encapsulation process as defined above, further comprising the steps of providing a tertiary capsule having a base and a cap; introducing at least one ingredient having a third physical state into said tertiary, capsule; positioning said cap of said secondary capsule in sealing relationship with said base; and introducing said tertiary capsule into said base of said secondary capsule.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said ingredient in said tertiary capsule is selected from the group consisting of a pharmaceutical, a biotechnical, a nutraceutical, a vitamin, a dietary supplement and a mineral.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said ingredient in said tertiary capsule comprises a physical state selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said tertiary capsule comprises a time-release coating.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said lubricant is selected from the group consisting of aluminumstearate, calciumstearate, magnesiumstearate, tinstearate, talc, sodium lauryl sulfate, lecithins, mineral oils, stearic acid, silicones and combinations thereof.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said primary and secondary capsules are formed having different colors.

In another embodiment of the present invention, there is an encapsulation process for forming a multi-compartment capsule, said process comprising the steps of providing a capsule comprising a cap, a base configured having a longitudinally extending body including a length and at least one dividing wall formed along said length of said extending body, said dividing wall adapted to form a first receiving chamber and a second receiving chamber; introducing at least one ingredient having a first physical state into said second receiving chamber; introducing at least one ingredient having a second physical state into said first receiving chamber, wherein said first physical state of said ingredient of said second receiving chamber being different from said second physical state of said ingredient of said first receiving chamber; and positioning said cap in sealing relationship with said base.

In another embodiment of the present invention, there is an encapsulation process as defined above, further comprising the step of reducing dead volume space within said primary capsule.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said filling material is selected from the group consisting of gelatin, starch, casein, chitosan, soya bean protein, safflower protein, alginates, gellan gum, carrageenan, xanthan gum, phtalated gelatin, succinated gelatin, cellulosephthalate-acetate, polyvinylacetate, hydroxypropyl methyl cellulose, polyvinylacetate-phtalate, polymerisates of acrylic or methacrylic esters and combinations thereof.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said cap comprises a configuration sufficient for reducing dead volume space within said capsule.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said ingredient in said first receiving chamber is selected from the group

25

consisting of a pharmaceutical, a biotechnical, a nutraceutical, a vitamin, a dietary supplement and a mineral.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said physical state of said ingredient in said receiving chamber is selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said ingredient in said second receiving chamber is selected from the group consisting of a pharmaceutical, a biotechnical, a nutraceutical, a vitamin, a dietary supplement and a mineral.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said physical state of said ingredient in said second receiving chamber is selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said ingredient in said first receiving chamber comprises a pharmaceutical and said ingredient in said second receiving chamber is selected from the group consisting of a pharmaceutical.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said time-release coating of said second receiving chamber is different from said time-release coating of said first receiving chamber.

In another embodiment of the present invention, there is an encapsulation process as defined above, further comprising the steps of positioning a second dividing wall along said length of said extending body of said base, said second dividing wall adapted to form a third receiving chamber; and introducing at least one ingredient having a physical state into said third receiving chamber.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said ingredient introduced into said third receiving chamber is selected from the group consisting of a pharmaceutical, a biotechnical, a nutraceutical, a vitamin, a dietary supplement and a mineral.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said physical state of said ingredient introduced into said third receiving chamber is selected from the group consisting of a solid, a liquid, a gas and a dispersion.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said second dividing wall comprises a time-release coating.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said capsule further comprises a soft elastic capsule formed of a material selected from the group consisting of glycerin and sorbitol.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said lubricant is selected from the group consisting of aluminiumstearate, calciumstearate, magnesiumstearate, tinstearate, talc, sodium lauryl sulfate, lecithins, mineral oils, stearic acid, silicones and combinations thereof.

In another embodiment of the present invention, there is an encapsulation process as defined above, wherein said base and said cap of said capsule are formed having different colors.

#### BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects and features of the present invention will become more fully apparent from the following description and appended claims, taken in conjunction with the accompanying drawings. Understanding that these draw-

26

ings depict only typical embodiments of the invention and are, therefore, not to be considered limiting of its scope, the invention will be described with additional specificity and detail through use of the accompanying drawings in which:

FIG. 1 is a flow diagram illustrating one presently preferred embodiment of a process of the present invention comprising the steps of introducing at least one active ingredient or medicament having a solid physical state into a secondary capsule and introducing the secondary capsule into a primary capsule further including at least one active ingredient or medicament having a liquid physical state;

FIG. 2 is a cross-sectional view illustrating another presently preferred embodiment of a multi-compartment capsule of the present invention wherein a primary capsule houses a secondary capsule and a secondary capsule houses a tertiary capsule, wherein each of the capsules include one or more active ingredients or medicaments and the active ingredient(s) introduced into at least two of the capsules comprise different physical states;

FIG. 3 is a perspective view illustrating yet another presently preferred embodiment of a multi-compartment capsule comprising a base, a cap and a dividing wall positioned between the base and the cap, wherein the dividing wall facilitates the formation of at least two, independent receiving chambers for receiving one or more active ingredients or medicaments having different physical states;

FIG. 4 is a cross-sectional view of the multi-compartment capsule shown in FIG. 3 wherein the base, the dividing wall defining the two receiving chambers and the cap are assembled to form a capsule of the present invention and wherein one or more active ingredients or medicaments having different physical states are introduced into the receiving chambers;

FIG. 5 is a perspective view illustrating an alternate presently preferred embodiment of a multi-compartment capsule of the present invention having a primary capsule comprising a capsular base configured with a longitudinally extending body, a corresponding cap and a series of dividing walls disposed in spaced apart relationship along the length of the longitudinally extending body of the base, wherein the dividing walls define a plurality of independent receiving chambers having an internal periphery sufficient for introducing one or more active ingredients or medicaments having different physical states therein and for introducing a secondary capsule, having one or more active ingredients contained therein, within at least one of said receiving chambers;

FIG. 6 is a cross-sectional view of the multi-compartment capsule shown in FIG. 5 wherein the base and the cap are assembled to form a single dosage capsule having a series of dividing walls that define a plurality of chambers for receiving one or more active ingredients or medicaments, wherein the active ingredient(s) in at least two of the receiving chambers comprise different physical states;

FIG. 7 is a perspective view illustrating yet another presently preferred embodiment of a multi-compartment capsule of the present invention having a primary capsule comprising a capsular base configured with a longitudinally extending body, a corresponding cap and a series of dividing walls disposed in spaced apart relationship, both vertically and horizontally, along the length of the longitudinally extending body of the base, wherein the dividing walls define a plurality of independent receiving chambers having an internal periphery sufficient for introducing one or more active ingredients or medicaments having different physical states therein;

FIG. 8 is a perspective view illustrating an alternate presently preferred embodiment of the multi-compartment capsule shown in FIG. 7, wherein the multi-compartment capsule includes a

27

primary capsule comprising a capsular base configured with a longitudinally extending body, a corresponding cap and a series of dividing walls disposed in spaced apart relationship, both vertically and horizontally, along the length of the longitudinally extending body of the base, wherein the dividing walls define a plurality of independent receiving chambers having an internal periphery sufficient for introducing one or more active ingredients or medicaments having different physical states therein and for introducing a secondary capsule, having one or more active ingredients contained therein, within at least one of said receiving chambers;

FIG. 9 is a perspective view illustrating yet another presently preferred embodiment of a multi-compartment capsule of the present invention wherein the multi-compartment capsule shown in FIG. 7 is introduced within the internal periphery of a receiving chamber of a primary capsule having one or more active ingredients also contained therein;

FIG. 10 is a cross-sectional view illustrating a presently preferred embodiment of a multi-compartment capsule of the present invention including a secondary capsule having one or more active ingredients or medicaments selectively introduced into the internal periphery of a primary capsule having one or more active ingredients or medicaments, wherein the active ingredient(s) introduced into the primary capsule comprises a physical state (e.g., solid, liquid, gas or dispersion) which differs from the physical state of the active ingredient(s) introduced into the internal periphery of the secondary capsule, the primary capsule further comprising a cap having a generally U-shaped configuration adapted to provide a sealing relationship when engaging the corresponding base, thereby reducing dead space volume in the internal periphery of the receiving chamber of the base;

FIG. 11 is a perspective view illustrating yet another presently preferred embodiment of a multi-compartment capsule of the present invention including a secondary capsule having one or more active ingredients or medicaments and having a size and shape sufficient for being selectively introduced into the internal periphery of a primary capsule having one or more active ingredients or medicaments, wherein the active ingredient(s) introduced into the primary capsule comprises a physical state (e.g., solid, liquid, gas or dispersion) which differs from the physical state of the active ingredient(s) introduced into the internal periphery of the secondary capsule, the primary capsule further comprising a filling material introduced into the internal periphery of the cap having a general conical configuration and adapted to provide a sealing relationship when engaging the corresponding base, thereby reducing dead space volume in the internal periphery of the receiving chamber of the base;

FIG. 12 is a cross-sectional view of the multi-compartment capsule shown in FIG. 11 wherein a sufficient amount of filling material is introduced into the internal periphery of the cap, thereby functioning to eliminate or significantly reduce the dead space volume in the receiving chamber of the primary capsule; and

FIG. 13 is a cross-sectional view illustrating an alternate presently preferred embodiment of a multi-compartment capsule of the present invention comprising a tertiary capsule having one or more active ingredients or medicaments and having a size a shape sufficient for being introduced into at least a portion of the internal periphery of the receiving chamber of a secondary capsule having one or more active ingredients or medicaments also introduced therein, the size and shape of the secondary capsule sufficient for being selectively introduced into the internal periphery of a primary capsule having one or more active ingredients or medicaments, wherein the active ingredient(s) introduced into the primary

28

capsule comprises a physical state (e.g., solid, liquid, gas or dispersion) which differs from the physical state of the active ingredient(s) introduced into the receiving chambers of the secondary and tertiary capsules, the primary capsule further comprising a filling material introduced into the internal periphery of the cap having a general conical configuration and adapted to provide a sealing relationship when engaging the corresponding base, thereby reducing dead space volume in the internal periphery of the receiving chamber of the base of the primary capsule.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

It will be readily understood that the components of the present invention, as generally described and illustrated in the Figures herein, could be arranged and designed in a wide variety of different configurations and process steps. Those of ordinary skill in the art will, of course, appreciate that various modifications to the details herein may easily be made without departing from the essential characteristics of the invention, as described. Thus, the following more detailed description of the embodiments of apparatus and methods of the present invention, as represented in FIGS. 1 through 13, is not intended to limit the scope of the invention, as claimed, but it is merely representative of the presently preferred embodiments of the invention.

The presently preferred embodiments of the invention will be best understood by reference to the drawings, wherein like parts are designated by like numerals throughout.

One presently preferred embodiment of the present invention, designated generally at 10, is best illustrated in FIG. 1. As shown, a multi-compartment capsule 10 is illustrated comprising a primary capsule 11 and a secondary capsule 20 selectively introduced within at least a portion of an internal periphery of the primary capsule. The secondary capsule 20 includes a base 24, a corresponding cap 22 and a receiving chamber 28 formed between the base and cap. The receiving chamber 28 is configured having an internal periphery sufficient for receiving at least one active ingredient or medication (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) therein. In similar structural design, the primary capsule 11 may be formed having a base 14, a corresponding cap 12 and a receiving chamber 18 formed between the base and cap. The receiving chamber 18 of the primary capsule 11 is preferably formed having an internal periphery sufficient for receiving the secondary capsule 20, together with at least one active ingredient or medication (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) therein.

Still referring to FIG. 1, one presently preferred embodiment of an encapsulation process for forming a multi-compartment capsule 10 is comprising the steps of: (1) providing a primary capsule 11 having a base 14, a corresponding cap 12 and a receiving chamber 18; (2) providing a secondary capsule 20 having a base 24, a corresponding cap 22 and a receiving chamber 28; (3) introducing at least one ingredient or medication (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) having a first physical state (e.g., solid, liquid, gas or dispersion) into at least a portion of the receiving chamber 28 of the secondary capsule 20 and selectively positioning the cap 22 in sealing relationship with the base 24; (4) introducing at least one ingredient or medication (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) having a second

physical state (e.g., solid, liquid, gas or dispersion) into at least a portion of the receiving chamber **18** of the primary capsule **11**, wherein the first physical state of the ingredient(s) in the secondary capsule is different from the second physical state of the ingredient(s) in the primary capsule; and (5) introducing the secondary capsule **20** into at least a portion of the receiving chamber **18** of the primary capsule **11** and selectively positioning the cap **12** in sealing relationship with the base **14** to form a single dosage multi-compartment capsule.

As shown, a solid is selectively introduced within at least a portion of the internal periphery of the receiving chamber **28** of the secondary capsule **20** and a liquid is selectively introduced within at least a portion of the internal periphery of the receiving chamber **18** of the primary capsule **11**. Although the ingredient(s) introduced into the receiving chamber **18** of the primary capsule **11** may be the same or different from the ingredient(s) introduced into the receiving chamber **28** of the secondary capsule, the active ingredient(s) in the primary capsule **11** have a physical state (i.e., solid, liquid, gas or dispersion) that varies from the physical state of the active ingredient(s) in the secondary capsule **20**. Accordingly, those skilled in the art will readily recognize other possible modifications and adaptations relative to the contemplated variations in physical states of the active ingredient(s) selectively positionable within the receiving chambers **18**, **28** of the primary and secondary capsules, respectively, which are consistent with the spirit and scope of the present invention. It is intended, therefore, that the figures and examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or method for implementing those principles.

Referring now to FIG. 2, an alternate presently preferred embodiment of a multi-compartment capsule **110** is shown comprising a primary capsule **111**, a secondary capsule **120** and a tertiary capsule **130**. The tertiary capsule **130** includes a base **134**, a corresponding cap **132** and a receiving chamber **138** formed between the base and cap. The receiving chamber **138** is preferably formed having an internal periphery sufficient for receiving at least one active ingredient or medication (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof). Structurally, the tertiary capsule **130** is configured having a size sufficient for being selectively introduced within at least a portion of an internal periphery of a receiving chamber **128** defined between a base **124** and a corresponding cap **122** of the secondary capsule **120**. One or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) may be introduced into at least a portion of the receiving chamber **128** of the secondary capsule **120**, together with the introduction of the tertiary capsule **130** comprising its active ingredient(s). The secondary capsule **120** having its active ingredient(s) and housing the tertiary capsule **130** with its active ingredient(s) may then be selectively introduced within at least a portion of an internal periphery of a receiving chamber **118** of the primary capsule **111** defined between a base **114** and a corresponding cap **112**. Preferably, the receiving chamber **118** of the primary capsule **111** may also include one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) introduced therein.

Still referring to FIG. 2, another presently preferred embodiment of an encapsulation process for forming a multi-compartment capsule **110** may comprise the steps of: (1) providing a primary capsule **111** having a base **114**, a corre-

sponding cap **112** and a receiving chamber **118** defined between the base and cap; (2) providing a secondary capsule **120** having a base **124**, a corresponding cap **122** and a receiving chamber **128** defined between the base and cap; (3) providing a tertiary capsule **130** having a base **134**, a corresponding cap **132** and a receiving chamber **138** defined between the base and cap; (4) introducing at least one ingredient (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) having a first physical state (e.g., solid, liquid, gas or dispersion) into at least a portion of the receiving chamber **138** of the tertiary capsule **130** and selectively positioning the cap **132** in sealing relationship with the base **134**; (5) introducing at least one ingredient (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) having a second physical state (e.g., solid, liquid, gas or dispersion) into at least a portion of the receiving chamber **128** of the secondary capsule **120**, wherein the first physical state of the ingredient(s) in the tertiary capsule **130** are the same as the second physical state of the ingredient(s) in the secondary capsule **120**; (6) introducing the tertiary capsule **130** into at least a portion of the receiving chamber **218** of the secondary capsule **120** and selectively positioning the cap **122** in sealing relationship with the base **124**; (7) introducing at least one ingredient (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) having a third physical state (e.g., solid, liquid, gas or dispersion) into at least a portion of the receiving chamber **118** of the primary capsule **111**, wherein the third physical state of the ingredient(s) in the primary capsule are different from the first and second physical states of the ingredient(s) in the tertiary capsule **130** and the secondary capsule **120**, respectively; and (8) introducing the secondary capsule **120** into at least a portion of the receiving chamber **118** of the primary capsule **111** and selectively positioning the cap **112** in sealing relationship with the base **114** to form a single dosage multi-compartment capsule.

In the presently preferred embodiment illustrated in FIG. 2, a liquid may be selectively introduced into at least a portion of the internal periphery of the receiving chamber **118** of the primary capsule **111**, a solid may be selectively introduced into at least a portion of the internal periphery of the receiving chamber **128** of the secondary capsule **120** and a solid may be selectively introduced into at least a portion of the receiving chamber **138** of the tertiary capsule **130**. Although the ingredient(s) selectively introduced into the receiving chambers **118**, **128**, **138** of the primary, secondary and tertiary capsules **111**, **120**, **130**, respectively, may be the same or different, the active ingredient(s) in at least two of the receiving chambers comprise at least two different physical states (e.g., solid, liquid, gas or dispersion). It is further contemplated herein as an alternate embodiment that the active ingredient(s) introduced in the receiving chamber **118** of the primary capsule **111** comprises a physical state (e.g., solid, liquid, gas or dispersion) different from the physical state of the active ingredient(s) contained within the receiving chamber **128** of the secondary capsule **120** which is different from the physical state of the active ingredient(s) contained within the receiving chamber **138** of the tertiary capsule **130**. Those skilled in the art will readily recognize other possible modifications and adaptations relative to contemplated variations in physical states of the active ingredient(s) selectively introduced within the receiving chambers **118**, **128**, **138** of the primary, secondary and tertiary capsules, respectively, which are consistent with the spirit and scope of the present invention. It is intended, therefore, that the figures and examples provided herein be viewed as exemplary of the principles of

31

the present invention, and not as restrictive to a particular structure or method for implementing those principles.

Referring now to FIGS. 3 and 4, another presently preferred embodiment of a multi-compartment capsule 210 is shown comprising a base 214, a corresponding cap 212 and a dividing wall 216 positionable between the base and the cap. Structurally, the size, shape and positioning of the dividing wall 216 relative to the base 214 and corresponding cap 212 facilitates the formation of at least two, independent and separate receiving chambers 218a, 218b, each having an internal periphery sufficient for receiving one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) therein. As best shown in FIG. 4, the dividing wall 216 seats within the internal periphery of both the base 214 and the corresponding cap 212. After introducing one or more active ingredients or medicaments into receiving chamber 218b and disposing the dividing wall 216 relative thereto, one or more active ingredients or medicaments (e.g. pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) may be introduced into receiving chamber 218a and the cap may be selectively positioned in sealing relationship with the base 214 to form one presently preferred embodiment of the single, dosage multi-compartment capsule 210. Moreover, the dividing wall 216 may functionally assist in forming a sealing relationship between the base 214 and corresponding cap 212 of the multi-compartment capsule 210, if desired.

In one presently preferred embodiment of the multi-compartment capsule 211 of the present invention, a solid may be selectively introduced into at least a portion of the internal periphery of the receiving chamber 218a and a liquid may be selectively introduced into at least a portion of the internal periphery of the receiving chamber 218b. Although the ingredient(s) introduced into the receiving chamber 218a may be the same or different from the ingredient(s) introduced into the receiving chamber 218, the active ingredient(s) in the first receiving chamber 218a preferably comprise a physical state (e.g., solid, liquid, gas or dispersion) that is different from the physical state of the active ingredient(s) in the second receiving chamber 218b. Those skilled in the art will readily recognize other possible modifications and adaptations relative to the contemplated variations in physical states (e.g., solid, liquid, gas and dispersion) of the active ingredient(s) selectively positionable within the receiving chambers 218a, 218b which are consistent with the spirit and scope of the present invention. It is intended, therefore, that the figures and examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or method for implementing those principles.

Referring now to FIGS. 5 and 6, another presently preferred embodiment of a multi-compartment capsule, designated as 310, is shown including a primary capsule 311 comprising a capsular base 314 configured having an elongated or longitudinally extending body, a corresponding cap 312 and a plurality of dividing walls 316 selectively disposed along the length of the longitudinally extending body of the base. Preferably, the structural size, shape and positioning of the dividing walls 316a, 316b, 316c along the length of the elongated body of the base 314 facilitate the formation of a plurality of independent receiving chambers 318a, 318b, 318c, 318d. Each receiving chamber 318a, 318b, 318c, 318d of the primary capsule 311 having an internal periphery sufficient for receiving one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) therein.

32

As best shown in FIG. 6, the dividing walls 316a, 316b, 316c are preferably seated within the internal periphery of the base 314 of the primary capsule 311 and in a spaced apart relationship along the length of the longitudinally extending body and form four independent receiving chambers 318a, 318b, 318c, 318d. In one presently preferred embodiment of the multi-compartment capsule 310 of the present invention, each of the receiving chambers 318a, 318b, 318c comprises at least one active ingredient or medicament having a physical state (e.g., solid, liquid, gas or dispersion) different from the physical state of the ingredient(s) in the other receiving chambers.

As illustrated by way of example, and not by way of restriction, a solid may be selectively introduced into at least a portion of the internal periphery of the receiving chamber 318a, a dispersion may be selectively introduced into at least a portion of the internal periphery of the receiving chamber 318b, a liquid may be selectively introduced into at least a portion of the internal periphery of the receiving chamber 318c and a secondary, capsule 320 may be selectively introduced into at least a portion of the internal periphery of the receiving chamber 318d. As contemplated herein, receiving chamber 318d may be further configured having an internal periphery sufficient for receiving a secondary capsule 320, together with at least one active ingredient or medicament therein.

One presently preferred embodiment of an encapsulation process, as defined by the structural configuration of the multi-compartment capsule 310 illustrated in FIGS. 5 and 6, may comprise the steps of: (1) introducing a secondary capsule 320 (e.g., tablet) and one or more active ingredients or medicaments into receiving chamber 318d; (2) selectively positioning dividing wall 316c along the length of the elongated body of the base 314; (3) introducing one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) into receiving chamber 318c; (4) selectively positioning dividing wall 316b along the length of the elongated body of the base 314 in a spaced apart relationship to dividing wall 316c; (5) introducing one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) into receiving chamber 318b; (6) selectively positioning dividing wall 316a along the length of the elongated body of the base 314 in a spaced apart relationship to dividing wall 316b; and (7) selectively positioning the cap 312 in sealing relationship with the base 314 to form a presently preferred embodiment of a single, dosage multi-compartment capsule 310. The dividing wall 316a may also function in the formation of the sealing relationship between the base 314 and the corresponding cap 312, if desired.

Although the ingredient(s) introduced into one of the receiving chambers 318 may be the same ingredient or may be different from the ingredient(s) introduced into the other receiving chambers, the active ingredient(s) in at least two of the receiving chambers 318 preferably comprise a physical state (e.g., solid, liquid, gas or dispersion) that is different from the physical state of the active ingredient(s) in one or more of the remaining receiving chambers. Those skilled in the art will readily recognize other possible modifications and adaptations relative to the contemplated variations in physical states (e.g., solid, liquid, gas and dispersion) of the active ingredient(s) selectively introduced within the receiving chambers 318 which are consistent with the spirit and scope of the present invention. It is intended, therefore, that the figures and examples provided herein be viewed as exemplary

of the principles of the present invention, and not as restrictive to a particular structure or method for implementing those principles.

Another presently preferred embodiment of a multi-compartment capsule of the present invention, generally designated as **410** in FIG. 7, is shown comprising a capsular base **414** preferably configured having an elongated or longitudinally extending body, a corresponding cap **412** and a plurality of dividing walls **416** selectively disposed along the length of the longitudinally extending body of the base, both horizontally and vertically. In structural design, the size, shape and positioning of the dividing walls **416a**, **416b**, **416c**, **416d**, **416e** along the length of the longitudinally extending body of the base **414** facilitate the formation of a plurality of independent receiving chambers **418**.

In one presently preferred embodiment, the dividing walls **416a**, **416b**, **416c**, **416d**, **416e** are preferably disposed or seated in a spaced apart relationship within the internal periphery of the base **414** of the primary capsule **411** along the length of the longitudinally extending body, whereby forming five (5) independent receiving chambers **418a**, **418b**, **418c**, **418d**, **418e**. Each receiving chamber **418a**, **418b**, **418c**, **418d**, **418e** of the primary capsule **411** are preferably configured having an internal periphery dimensionally sufficient for receiving one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) therein.

Still referring to FIG. 7, one presently preferred embodiment of an encapsulation process, as defined by the structural configuration of the multi-compartment capsule **410**, may comprise the steps of: (1) introducing one or more active ingredients or medicaments into receiving chamber **418e** defined by dividing walls **416d**, **416e** which are vertically disposed along the length of the elongated body of the base **414**; (2) introducing one or more active ingredients or medicaments into receiving chamber **418d** defined by dividing walls **416c**, **416d** which are vertically disposed along the length of the elongated body of the base **414**; (3) introducing one or more active ingredients or medicaments into receiving chamber **418c** defined by dividing walls **416b**, **416c** which are vertically disposed along the length of the elongated body of the base **414**; (4) introducing one or more active ingredients or medicaments into receiving chamber **418b** defined by dividing walls **416b**, **416e** which are vertically disposed along the length of the elongated body of the base **414**; (5) disposing dividing wall **416a** along the length of the elongated body of the base **414** perpendicular to the disposition of dividing walls **416b**, **416c**, **416d**, **416e** and introducing one or more active ingredients or medicaments into receiving chamber **418a**; and (6) selectively positioning the cap **412** in sealing relationship with the base **414** to form one presently preferred embodiment of a single, dosage multi-compartment capsule **410**. As appreciated, the dividing wall **416a** may also function in the formation of the sealing relationship between the base **414** and the corresponding cap **412**, if structurally desired.

As illustrated by way of example, and not by way of restriction, a solid may be selectively introduced into at least a portion of the internal periphery of the receiving chamber **418a**, a dispersion may be selectively introduced into at least a portion of the internal periphery of the receiving chamber **418b**, a liquid may be selectively introduced into at least a portion of the internal periphery of the receiving chamber **418c**, a solid may be selectively introduced into at least a portion of the internal periphery of the receiving chamber **418d** and a liquid may be selectively introduced into at least a portion of the internal periphery of the receiving chamber **418e**.

Although the ingredient(s) introduced into one of the receiving chambers **418** may be the same ingredient or may be different from the ingredient(s) introduced into the other receiving chambers, the active ingredient(s) in at least two of the receiving chambers **418** preferably comprise a physical state (e.g., solid, liquid, gas or dispersion) that is different from the physical state of the active ingredient(s) in one or more of the remaining receiving chambers. Those skilled in the art will readily recognize other possible modifications and adaptations relative to the contemplated variations in physical states (e.g., solid, liquid, gas and dispersion) of the active ingredient(s) selectively introduced within the receiving chambers **418** which are consistent with the spirit and scope of the present invention. It is intended, therefore, that the figures and examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or method for implementing those principles.

Referring now to FIG. 8, an alternate presently preferred embodiment of a multi-compartment capsule **510** includes a capsular base **514** preferably configured having an elongated or longitudinally extending body, a corresponding cap **512** and a plurality of dividing walls **516** selectively disposed along the length of the longitudinally extending body of the base, both horizontally and vertically. In structural design, the size, shape and positioning of the dividing walls **516a**, **516b**, **516c**, **516d** along the length of the longitudinally extending body of the base **514** facilitate the formation of a plurality of independent receiving chambers **518**.

In one presently preferred embodiment, the dividing walls **516a**, **516b**, **516c**, **516d**, **516e** are preferably disposed or seated in a spaced apart relationship within the internal periphery of the base **514** of the primary capsule **511** along the length of the longitudinally extending body, whereby forming five (5) independent receiving chambers **518a**, **518b**, **518c**, **518d**, **518e**. Each of the receiving chamber **518a**, **518b**, **518c**, **518d**, **518e** of the primary capsule **511** are preferably configured having an internal periphery dimensionally sufficient for receiving one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) therein. Moreover, receiving chamber **518d** is formed having an internal periphery sufficient for receiving a secondary capsule **520**. The secondary capsule **520** being configured with a base **524**, corresponding cap **522** and a dividing wall **526** defining a first receiving chamber **528a** and a second receiving chamber **528b**. The first receiving chamber **528a** is preferably configured having an internal periphery sufficient for receiving one or more active ingredients or medicaments (e.g. pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) having a first physical state (e.g., solid, liquid, gas or dispersion) therein. Similarly, the second receiving chamber **528b** is configured having an internal periphery sufficient for receiving one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) having a second physical state (e.g., solid, liquid, gas or dispersion), wherein the physical state of the ingredient(s) in the second receiving chamber varies from the physical state of the ingredient(s) in the first receiving chamber. As contemplated and disclosed hereinabove, after the ingredients are introduced into the respective receiving chamber **528a**, **528b**, the cap **522** may be positioned in sealing relationship with the base **524** of the secondary capsule **520**.

Still referring to FIG. 8, as illustrated by way of example, and not by way of restriction, a solid may be selectively

introduced into at least a portion of the internal periphery of the receiving chamber **528a** and a liquid may be selectively introduced into at least a portion of the internal periphery of the receiving chamber **528b**. Although the ingredient(s) introduced into one of the receiving chamber **528a** may be the same ingredient or maybe different from the ingredient(s) introduced into receiving chamber **528b**, the active ingredient(s) in the first receiving chamber **528a** comprise a physical state (e.g., solid, liquid, gas or dispersion) that is different from the physical state of the active ingredient(s) in receiving chambers **528b**. Those skilled in the art will readily recognize other possible modifications and adaptations relative to the contemplated variations in physical states (e.g., solid, liquid, gas and dispersion) of the active ingredient(s) selectively introduced within the receiving chambers **528** which are consistent with the spirit and scope of the present invention. It is intended, therefore, that the figures and examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or method for implementing those principles

One presently preferred embodiment of an encapsulation process, as defined by the structural configuration of the multi-compartment capsule **510**, may comprise the steps of: (1) introducing one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) into receiving chamber **518e** defined by dividing walls **516d**, **516e** which are disposed vertically along the length of the elongated body of the base **514**; (2) introducing a secondary capsule **520** into receiving chamber **518d** defined by dividing walls **516c**, **516d** which are disposed vertically along the length of the elongated body of the base **514**; (3) introducing one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) into receiving chamber **518c** defined by dividing walls **516b**, **516c** which are disposed vertically along the length of the elongated body of the base **514**; (4) introducing one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) into receiving chamber **518b** defined by dividing walls **516b**, **516e** which are disposed vertically along the length of the elongated body of the base **514**; (5) disposing dividing wall **516a** along the length of the elongated body of the base **514** perpendicular to the disposition of dividing walls **516b**, **516c**, **516d**, **516e** and introducing one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) into receiving chamber **518a**; and (6) selectively positioning the cap **512** in sealing relationship with the base **514** to form one presently preferred embodiment of a single, dosage multi-compartment capsule **510**. As appreciated, the dividing wall **516a** may also function in the formation of the sealing relationship between the base **514** and the corresponding cap **512**, if structurally desired.

As illustrated by way of example, and not by way of limitation, a solid may be selectively introduced into at least a portion of the internal periphery of receiving chamber **518a**, a dispersion may be selectively introduced into at least a portion of the internal periphery of receiving chamber **518b**, a liquid may be selectively introduced into at least a portion of the internal periphery of the receiving chamber **518c** and a liquid may be selectively introduced into at least a portion of the internal periphery of the receiving chamber **518e**. Although the ingredient(s) introduced into one of the receiving chambers **518** may be the same ingredient or may be different from the ingredient(s) introduced into the other

receiving chambers, the active ingredient(s) in at least two of the receiving chambers **518** preferably comprise a physical state (e.g., solid, liquid, gas or dispersion) that is different from the physical state of the active ingredient(s) in one or more of the remaining receiving chambers. Those skilled in the art will readily recognize other possible modifications and adaptations relative to the contemplated variations in physical states (e.g., solid, liquid, gas and dispersion) of the active ingredient(s) selectively introduced within the receiving chambers **518** which are consistent with the spirit and scope of the present invention. It is intended, therefore, that the figures and examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or method for implementing those principles.

Referring now to FIG. 9, yet another presently preferred embodiment of a multi-compartment capsule of the present invention, generally designated as **610**, is shown comprising a primary capsule **611** and a secondary capsule **620** selectively positionable within at least a portion of an internal periphery of the primary capsule. The primary capsule **611** having a receiving chamber **618** preferably formed having an internal periphery sufficient for receiving the secondary capsule **620**, together with one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) therein. The secondary capsule **620** comprising a capsular base **624** preferably configured having an elongated or longitudinally extending body, a corresponding cap **622** and a plurality of dividing walls **626** selectively disposed along the length of the longitudinally extending body of the base, both horizontally and vertically. In structural design, the size, shape and positioning of the dividing walls **626a**, **626b**, **626c**, **626d** along the length of the longitudinally extending body of the base **624** facilitate the formation of a plurality of independent receiving chambers **628**.

In one presently preferred embodiment, the dividing walls **626a**, **626b**, **626c**, **626d**, **426e** are preferably disposed or seated in a spaced apart relationship within the internal periphery of the base **624** of the secondary capsule **620** along the length of the longitudinally extending body, whereby forming five (5) independent receiving chambers **628a**, **628b**, **628c**, **628d**, **628e**. Each receiving chamber **628a**, **628b**, **628c**, **628d**, **628e** of the secondary capsule **620** are preferably configured having an internal periphery dimensionally sufficient for receiving one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) therein.

One presently preferred embodiment of an encapsulation process, as defined by the structural configuration of the multi-compartment capsule **610**, may comprise the steps of: (1) introducing one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) into receiving chamber **628e** defined by dividing walls **626d**, **626e** which are vertically disposed along the length of the elongated body of the base **624**; (2) introducing one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) into receiving chamber **628d** defined by dividing walls **626c**, **626d** which are vertically disposed along the length of the elongated body of the base **624**; (3) introducing one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) into receiving chamber **628c** defined by dividing walls **626b**, **626c** which are vertically disposed along the length of the

elongated body of the base **624**; (4) introducing one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) into receiving chamber **628b** defined by dividing walls **626b**, **626e** which are vertically disposed along the length of the elongated body of the base **624**; (5) disposing dividing wall **626a** along the length of the elongated body of the base **624** perpendicular to the disposition of dividing walls **626b**, **626c**, **626d**, **626e** and introducing one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) into receiving chamber **628a**; (6) selectively positioning the cap **622** in sealing relationship with the base **624** of the secondary capsule **620**; (7) introducing the secondary capsule **620** and one or more ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) into the receiving chamber **618** of the primary capsule **611**; and (8) selectively positioning the cap **612** in sealing relationship with the base **614** of the primary capsule **611** to form one presently preferred embodiment of a single, dosage multi-compartment capsule **610**.

As illustrated by way of example, and not by way of restriction, a solid may be selectively introduced into at least a portion of the internal periphery of the receiving chamber **628a**, a dispersion may be selectively introduced into at least a portion of the internal periphery of the receiving chamber **628b**, a liquid may be selectively introduced into at least a portion of the internal periphery of the receiving chamber **628c**, a solid may be selectively introduced into at least a portion of the internal periphery of the receiving chamber **628d** and a liquid may be selectively introduced into at least a portion of the internal periphery of the receiving chamber **628e** of the secondary capsule **620**. In addition, a gas may be introduced into at least a portion of the internal periphery of the receiving chamber **618** of the primary capsule **611**.

Although the ingredient(s) introduced into one of the receiving chambers **618**, **628** of the primary and secondary capsules, respectively, may be the same ingredient or may be different from the ingredient(s) introduced into the other receiving chambers, the active ingredient(s) in at least two of the receiving chambers **618**, **628** preferably comprise a physical state (e.g., solid, liquid, gas or dispersion) that is different from the physical state of the active ingredient(s) in one or more of the remaining receiving chambers. Those skilled in the art will readily recognize other possible modifications and adaptations relative to the contemplated variations in physical states (e.g., solid, liquid, gas and dispersion) of the active ingredient(s) selectively introduced within the receiving chambers **618**, **628** which are consistent with the spirit and scope of the present invention. It is intended, therefore, that the figures and examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or method for implementing those principles.

Another presently preferred embodiment of a multi-compartment capsule of the present invention, generally designated as **710** in FIG. **10**, is shown comprising a secondary capsule **720** including one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) within at least a portion of the internal periphery of a receiving chamber **728** and having a size and shape sufficient for being selectively introduced within at least a portion of the internal periphery of a receiving chamber **718** of a primary capsule **711**. The primary capsule **711** also includes one or more active ingredients or medicaments (e.g., pharmaceutical,

biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) introduced within the internal periphery of the receiving chamber **718**, wherein the active ingredient(s) introduced into the primary capsule comprises a physical state (e.g., solid, liquid, gas or dispersion) which differs from the physical state of the active ingredient(s) introduced into the internal periphery of the secondary capsule. In structural design, the primary capsule **711** further comprises a cap **712** having a generally U-shaped configuration adapted to provide a sealing relationship when engaging the corresponding base **714**, thereby reducing dead space volume in the internal periphery of the receiving chamber **718** of the base. In this regard, the configuration of the cap **712** generally eliminates or substantially reduces the potential dead space volume within the internal periphery of the receiving chamber **718**, thus functionally negating the opportunity for reaction between an air bubble and the active ingredient(s) introduced into the base **714** of the primary capsule **711**.

One presently preferred embodiment of an encapsulation process, as defined by the structural configuration of the multi-compartment capsule **710**, may include the steps of: (1) introducing one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) into receiving chamber **728**; (2) selectively positioning the cap **722** in sealing relationship with the base **724** of the secondary capsule **720**; (3) introducing one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof), together with the secondary capsule **720**, into the receiving chamber **718** of the primary capsule **711**; and (4) selectively positioning the cap **712** having a general U-shaped configuration in sealing relationship with the base **714** of the primary capsule **711** to form a presently preferred embodiment of a single, dosage multi-compartment capsule **710**, wherein eliminating or substantially reducing dead space volume within the internal periphery of the receiving chamber **718**.

A solid is selectively introduced within at least a portion of the internal periphery of the receiving chamber **728** of the secondary capsule **720** and a liquid is selectively introduced within at least a portion of the internal periphery of the receiving chamber **718** of the primary capsule **711**. Although the ingredient(s) introduced into the receiving chamber **718** of the primary capsule **711** may be the same or different from the ingredient(s) introduced into the receiving chamber **728** of the secondary capsule **720**, the active ingredient(s) in the primary capsule have a physical state (i.e., solid, liquid, gas or dispersion) that various from the physical state of the active ingredient(s) in the secondary capsule. Accordingly, those skilled in the art will readily recognize other possible modifications and adaptations relative to the contemplated variations in physical states of the active ingredient(s) selectively introduced within the receiving chambers **718**, **728** of the primary and secondary capsules **711**, **720**, respectively, which are consistent with the spirit and scope of the present invention. It is intended, therefore, that the figures and examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or method for implementing those principles.

Referring now to FIGS. **11** and **12**, yet another presently preferred embodiment of a multi-compartment capsule **810** of the present invention is shown comprising a secondary capsule **820** including one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof)

within at least a portion of the internal periphery of a receiving chamber **828**. The secondary capsule **820** being preferably formed having a size and shape sufficient for being selectively introduced within at least a portion of the internal periphery of a receiving chamber **818** of a primary capsule **811**. Similarly, the primary capsule **811** includes one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) introduced within the internal periphery of the receiving chamber **818**, together with the secondary capsule **820**, wherein the active ingredient(s) introduced into the primary capsule comprises a physical state (e.g., solid, liquid, gas or dispersion) which differs from the physical state of the active ingredient(s) introduced into the internal periphery of the secondary capsule **820**.

In preferred structural design, the primary capsule **811** comprises a cap **812** having a general cylindrical configuration adapted to provide a sealing relationship when engaging the corresponding base **814** to form a single dosage, multi-compartment capsule **810**. An amount of filling material **840** may be introduced into the internal periphery of the cap **812** to fill, either partially or completely, the inner volume of the cap, thereby reducing the dead space volume in the internal periphery of the receiving chamber **818** of the base. In this regard, the configuration of the addition of the filler material **840** relative to the internal periphery of the cap **812** generally eliminates or substantially reduces the potential dead space volume within the internal periphery of the receiving chamber **818**, thus functionally negating the potential for a reaction between an air bubble and the active ingredient(s) introduced into the base **814** of the primary capsule **811**.

Preferably, the filling material **840** introduced into at least a portion of the internal periphery of the cap **812** may include a hydrophilic polymer, such as gelatin. It will be readily appreciated by those skilled in the art that other filling materials may be used, such as, for example, starch, casein, chitosan, soya bean protein, safflower protein, alginates, gellan gum, carageenan, xanthan gum, phthalated gelatin, succinated gelatin cellulosephthalate-acetate, polyvinylacetate, hydroxypropyl methyl cellulose, (HPMC), oleoresin, polyvinylacetate-phthalate, polymerisates of acrylic or methacrylic esters, and mixtures thereof, or the like, and/or combinations thereof. In other presently preferred embodiments of the present invention, the filling material **840** may include the introduction of an inert compound, for example, nitrogen gas into at least a portion of the internal periphery of the cap **811**. Based on the principals of eliminating or reducing the volume dead space in multi-compartment capsules disclosed herein, those skilled in the art will readily recognize other possible modifications and combinations which are consistent with the spirit and scope of the present invention. It is intended, therefore, that the examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or process for implementing those principles.

The filling material **840** introduced within at least a portion of the internal periphery of the cap **812** of the primary capsule **811** is generally intended to promote a binding contact with at least a portion of the cap **822** of the secondary capsule **820**, thereby seating at least a portion of the secondary capsule within the cap of the primary capsule and forming a molded appearance. As appreciated, the introduction of the filling material **840** into the cap **812** of the primary capsule **811** prior to the joining and sealing process may prevent the opportunity for a reaction between an air-bubble and the active medicament(s) within the receiving chamber **818** of the primary

capsule, while preserving the overall rounded shape of the multi-compartment capsule **910** for ease of swallowing by a consumer.

As best illustrated in FIG. **12**, one presently preferred embodiment of an encapsulation process, as defined by the structural configuration of the multi-compartment capsule **810**, may include the steps of: (1) introducing one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin; dietary supplement, mineral or combination thereof) into at least a portion of the receiving chamber **828**; (2) selectively positioning the cap **822** in sealing relationship with the base **824** of the secondary capsule **820**; (3) introducing one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof), together with the secondary capsule **820**, into at least a portion of the receiving chamber **818** of the primary capsule **811**; (4) introducing a filling material **840** into at least a portion of the internal periphery of the cap **812** (i.e., filling the cap); and (5) selectively positioning the cap **812** having a general conical configuration in sealing relationship with the base **814** of the primary capsule **811** to form one presently preferred embodiment of a single, dosage multi-compartment capsule **810**, wherein eliminating or substantially reducing dead space volume within the internal periphery of the cap **812** and the receiving chamber **818**, respectively.

A solid may be selectively introduced within at least a portion of the internal periphery of the receiving chamber **828** of the secondary capsule **820** and a liquid may be selectively introduced within at least a portion of the internal periphery of the receiving chamber **818** of the primary capsule **811**. Although the ingredient(s) introduced into the receiving chamber **818** of the primary capsule **811** may be the same or different from the ingredient(s) introduced into the receiving chamber **828** of the secondary capsule **820**, the active ingredient(s) in the primary capsule have a physical state (i.e., solid, liquid, gas or dispersion) that varies from the physical state of the active ingredient(s) in the secondary capsule. Accordingly, those skilled in the art will readily recognize other possible modifications and adaptations relative to the contemplated variations in physical states of the active ingredient(s) selectively introduced within the receiving chambers **818**, **828** of the primary and secondary capsules **811**, **820**, respectively, which are consistent with the spirit and scope of the present invention. It is intended, therefore, that the figures and examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or method for implementing those principles.

Referring now to FIG. **13**, another presently preferred embodiment of a multi-compartment capsule, generally designated at **910**, is shown comprising a tertiary capsule **930** including one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) within at least a portion of the internal periphery of a receiving chamber **938** and having a size and shape sufficient for being introduced into the internal periphery of a receiving chamber **928** of a secondary capsule **920**. The secondary capsule **920** having one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) introduced within at least a portion of the internal periphery of a receiving chamber **928**, together with the tertiary capsule **930**. The secondary capsule **920** preferably formed having a size and shape sufficient for being selectively introduced within at least a portion of the internal periphery of a receiving cham-

ber **918** of a primary capsule **911**. Similarly, the primary capsule **911** may include one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) introduced within the internal periphery of the receiving chamber **818**, together with the secondary capsule **920** which houses the tertiary capsule **930**. In one presently preferred embodiment, the active ingredient(s) introduced into the secondary capsule **920** comprises a physical state (e.g., solid, liquid, gas or dispersion) which differs from the physical state of the active ingredient(s) introduced into the internal periphery of the primary capsule **911** and the internal periphery of the tertiary capsule **930**.

In preferred structural design, the primary capsule **911** comprises a cap **912** having a general cylindrical configuration adapted to provide a sealing relationship when engaging the corresponding base **914** to form a single dosage, multi-compartment capsule **910**. An amount of filling material **940** may be introduced into at least a portion of the internal periphery of the cap **912** to fill, either partially or completely, the inner volume of the cap, thereby reducing the dead space volume in the cap and the internal periphery of the receiving chamber **918** of the base. In this regard, the configuration of the addition of the filler material **940** relative to the internal periphery of the cap **912** may generally eliminate or substantially reduce the potential dead space volume within the internal periphery of the receiving chamber **918**, thus functionally negating the potential for a reaction between an air bubble and the active ingredient(s) introduced into the base **914** of the primary capsule **911**.

Preferably, the filling material **940** introduced into at least a portion of the internal periphery of the cap **912** may include a hydrophilic polymer, such as gelatin. It will be readily appreciated by those skilled in the art that other filling materials may be used, such as, for example, starch, casein, chitosan, soya bean protein, safflower protein, alginates, gellan gum, carrageenan, xanthan gum, phtalated gelatin, succinated gelatin, cellulosephthalate-acetate, polyvinylacetate, hydroxypropyl methylcellulose, oleoresin, polyvinylacetate-phthalate, polymerisates of acrylic or methacrylic esters, and mixtures thereof, or the like, and/or combinations thereof. In other presently preferred embodiments of the present invention, the filling material **840** may include the introduction of an inert compound, for example, nitrogen gas into at least a portion of the internal periphery of the cap **912**. Based on the principals of eliminating or reducing the volume dead space in multi-compartment capsules disclosed herein, those skilled in the art will readily recognize other possible modifications and combinations which are consistent with the spirit and scope of the present invention. It is intended, therefore, that the examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or process for implementing those principles.

The filling material **940** introduced within at least a portion of the internal periphery of the cap **912** of the primary capsule **911** is generally intended to promote a binding contact with at least a portion of the cap **922** of the secondary capsule **920**, thereby seating at least a portion of the secondary capsule within the cap of the primary capsule and forming a molded appearance. As appreciated, the introduction of the filling material **940** into the cap **912** of the primary capsule **911** prior to the joining and sealing process tends to prevent the opportunity for a reaction between an air bubble and the active medicament(s) within the receiving chamber **918** of the pri-

mary capsule, while preserving the overall rounded shape of the multi-compartment capsule **910** for ease of swallowing by a consumer.

As best illustrated in FIG. **13**, one presently preferred embodiment of an encapsulation process, as defined by the structural configuration of the multi-compartment capsule **910**, may include, the steps of: (1) introducing one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof) into at least a portion of the receiving chamber **938** of a tertiary capsule **930**; (2) selectively positioning the cap **932** in sealing relationship with the base **934** of the tertiary capsule **930**; (3) introducing one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof), together with the tertiary capsule **930**, into at least a portion of the receiving chamber **928** of the secondary capsule **920**; (4) selectively positioning the cap **922** in sealing relationship with the base **924** of the secondary capsule **920**; (5) introducing one or more active ingredients or medicaments (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof), together with the secondary capsule **920**, into at least a portion of the receiving chamber **918** of the primary capsule **911**; (6) introducing a filling material **940** into at least a portion of the internal periphery of the cap **912** (i.e., preferably filling the cap); and (7) selectively positioning the cap **912** having a general conical configuration in seating relationship with at least a portion of the secondary capsule **920** and sealing the base **914** of the primary capsule **911** to form one presently preferred embodiment of a single, dosage multi-compartment capsule **910**, wherein eliminating or substantially reducing dead space volume within the internal periphery of the cap **912** and the receiving chamber **918**, respectively.

A solid may be introduced within at least a portion of the internal periphery of the receiving chamber **938** of the tertiary capsule **930**, a liquid may be introduced into at least a portion of the internal periphery of the secondary capsule **920** and a solid may be selectively introduced within at least a portion of the internal periphery of the receiving chamber **918** of the primary capsule **911**. Although the ingredient(s) introduced into the receiving chambers **918**, **928**, **938** of the primary, secondary and tertiary capsules **911**, **920**, **930**, respectively, may be the same or different from the ingredient(s) introduced into the other receiving chambers, the active ingredient(s) in at least two of the receiving chambers **918**, **928**, **938** have different physical states (i.e., solid, liquid, gas or dispersion). Those skilled in the art will readily recognize other possible modifications and adaptations relative to the contemplated variations in physical states of the active ingredient(s) selectively introduced within the receiving chambers **918**, **928**, **938** of the primary, secondary and tertiary capsules **911**, **920**, **930**, respectively, which are consistent with the spirit and scope of the present invention. It is intended, therefore, that the figures and examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or method for implementing those principles.

Generally referring to FIGS. **1-13**, the component parts of the presently preferred embodiments of the multi-compartment capsules (i.e., capsular base, corresponding cap and dividing walls) of the present invention may comprise a hydrophilic polymer, such as gelatin (marine or animal based product). Other suitable materials forming the capsules may include starch, casein, chitosan, soya bean protein, safflower protein, alginates, gellan gum, carageenan, xanthan gum,

phtalated gelatin, succinated gelatin, cellulosephthalate-acetate, polyvinylacetate, hydroxypropyl methyl cellulose (HPMC), oleoresins, polyvinylacetate-phthalate, polymerisates of acrylic or methacrylic esters, and mixtures thereof, or the like, and/or combinations thereof. The material comprising the capsular components may further include between about 0% to 40% of pharmaceutically acceptable plasticizers based upon the weight of the hydrophilic polymer. Plasticizers that may be employed include, for example and not by way of limitation, polyethylene glycol, glycerol, sorbitol, dioctyl-sodium sulfosuccinate, triethyl citrate, tributyl citrate, 1,2-propyleneglycol, mono-acetates, di-acetates, or triacetates of glycerol, mixtures thereof, or the like, and/or combinations thereof. As appreciated, plasticizers may also be used in the development of a soft elastic shell, often referred to as a soft gelatin capsule or "soft gel" capsule, for a primary capsule, a secondary capsule and/or a tertiary capsule.

The capsular shell material may contain pharmaceutically acceptable lubricants in the range of about 0% to 10%, based upon the weight of the hydrophilic polymer. Lubricants that may be used include, for example and not by way of limitation, aluminum stearate, calcium stearate, magnesiumstearate, tin stearate, talc, sodium lauryl sulfate, lecithins, mineral oils, stearic acid, silicones, mixtures thereof, or the like, and/or combinations thereof. One presently preferred embodiment of the multi-compartmental capsules of the present invention (e.g., primary capsule, secondary capsule, tertiary capsule, etc.) may include, for example, LICAPS® capsules (for poorly soluble compounds), VCAPS™ capsules (made from cellulosic raw materials), CONI-SNAP® capsules and PRESS-FIT® capsules which are all presently manufactured by Capsugel, a subsidiary of Pfizer, Inc.

In one presently preferred embodiment of an encapsulation process, the primary capsule may be kept under conditions of low humidity within a filling machine during the contemplated steps of rectifying and assembling. In certain embodiments, the primary capsule may contain moisture content in the range of approximately 0% to 6% of the total weight. Similarly, a secondary capsule, a tertiary capsule, etc. may be processed in the same manner as the primary capsule relative to conditions of low humidity during the steps of rectifying and assembling. As contemplated herein, a moisture content of approximately 0% to 3% by weight is preferable. However, capsules having a higher moisture content than those stated herein are certainly not outside the spirit and scope of the present invention.

As illustrated in FIGS. 1-9 and 11-13, the shape of the base and corresponding cap of the capsules (e.g., primary, secondary, tertiary, etc.) of the presently preferred embodiments of the multi-compartment capsules are configured having a general cylindrical shape which defines a diameter and length sufficient for the introduction of an internal smaller capsule or one or more dividing walls along the length of the capsular base. It is apparent that other geometrical configurations of the cap are likewise suitable and contemplated herein, such as the general U-shaped configuration of the cap shown in FIG. 10. It is intended, therefore, that the examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to any particular structure or configuration for implementing those principles.

In one presently preferred embodiment, the clearance between the primary capsule and the secondary capsule introduced within the internal periphery of the primary capsule is preferably greater than +0.2 mm. The clearance between the outer capsular walls of the secondary capsule and the inner capsular walls of the primary capsule (or the tertiary capsule

and the secondary capsule) may be in the range of about 0 mm to 0.5 mm, whereas the outer capsular walls of the secondary capsule or tertiary capsule may be in actual contact with the inner capsular walls of the primary capsule or secondary capsule, respectively. As appreciated, in an effort to structural facilitate independent receiving chambers on opposing sides of a dividing wall introduced within the internal periphery of a base of a capsule, the perimeter of the dividing wall preferably engages the inner capsular walls of the capsule to provide a sealing relationship there between.

As further contemplated herein, the inner capsular walls of a primary capsule may be treated with an adhesive sufficient to improve engagement between the primary capsule and the outer capsular walls of a secondary capsule. A suitable technique to apply an adhesive may be by way of spraying the same on the shells and capsules immediately before assembling the same. Suitable adhesives that may be used may include, for example, tackidex, an aqueous gelatin solution, or the like.

The primary, secondary or tertiary capsules, in accordance with the present invention, may be formed having the same or different colors. Moreover, the base and corresponding cap of a single capsule may be formed having different colors in an effort to enhance the aesthetics of the capsule to the consumer. In one presently preferred embodiment of a multi-compartment capsule of the present invention, the dosage may be banded, sealed or easily dividable in a contact area of the primary and secondary capsules or the sealing band may be color-coded to assist in branding, if desired.

It is further contemplated herein that a multi-compartment capsule of the present invention may comprise component parts of the capsule having various time-release coatings to facilitate the release and ultimately the absorption of those active ingredients introduced into the different receiving chambers of the multi-compartment capsule to release at different release rates. In particular, a primary capsule may be formed having a conventional time-release coating that dissolves and releases the active ingredient(s) contained therein before the timed-release of the active ingredient(s) contained within a secondary capsule. Likewise, the dividing walls disposed within the internal periphery of the base of a capsule may be formed having conventional time-release coatings that dissolve and release the active ingredients within each receiving chamber defined by the dividing walls at different rates, thereby delivering the active ingredients or medicaments contained within a multi-compartment capsule at different rates. Certain active ingredients or medicaments may, therefore, be delivered at a selected interval, while other ingredients may be released at a later interval. In this way, the novel design of the multi-compartment capsules of the present invention may facilitate precision delivery of active ingredients to targeted areas of the consumer.

The disclosure of secondary and tertiary capsules may be replaced with other forms of microencapsulation. Microencapsulation as previously described, refers to the process whereby minute parcels of a solid, liquid, gas or dispersion, introduced into one or more of the receiving chambers as active ingredient(s), are film-coated with a secondary material in order to shield the active ingredient from its surrounding environment. Microcapsules may measure from microns to several millimeters, whereas the main purpose being to facilitate the release of the active ingredients at different release rates.

The incorporation of time-release coatings to varying the release rates of the active ingredients of a multi-compartment capsule may be used to target key time intervals or events when the body may be most able to utilize the active ingre-

dients. In one presently preferred embodiment of the present invention, all of the active ingredients may be microencapsulated. In alternate presently preferred embodiments, only selected ingredients may be microencapsulated for delayed release, while other ingredients may be provided for immediate absorption. Thus, the incorporation of time-release coatings in the encapsulation process when forming a multi-compartment capsule may be specifically designed to fit the needs and desires of numerous different users having similar conditions that are being targeted for treatment.

As contemplated herein, the physical states of active ingredients are characterized into one of four different states (e.g., solid, liquid, gas or dispersion). These four different states are sometimes referred to as "phases" (i.e., solid phase, liquid phase, gas phase or dispersion phase). For purposes of the present invention, the term "solid" is defined as including, by way of example only and not by way of limitation, pills, tablets, capsules (including both hard and soft elastic), powders, granulation, flakes, troches (lozenges and pastilles), suppositories and semi-solid pastes, ointments, emulsions or creams. The term "liquid" is defined as including, by way of example only and not by way of limitation, solutions, spirits, elixirs, sprays, syrups or fluid extracts. The term "dispersion" is defined as including, by way of example only and not by way of limitation, aerosols (liquid or solid in gas), suspensions (solid in liquid), emulsions (liquid in liquid), foams (gas in liquid), solid foams (solid in gas) or gels (liquid or solid in solid).

The active ingredients or medicaments introduced into the receiving chambers of the multi-compartment capsules of the present invention preferably comprise a pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof. For purposes of the present invention, the term "pharmaceutical" is defined as any substance that affects the structure or functioning of a living organism. Pharmaceuticals, sometimes referred to as "drugs" are widely used for the prevention, diagnosis and treatment of diseases and for the relief of symptoms. The term "biotechnical" is defined as any substance that is derived from a biotechnology process. Biotechnology, sometimes shortened to "biotech", is the development of techniques and methods (e.g., genetic engineering, protein engineering, genomics, proteomics, monoclonal antibody production, polymerase chain reaction, transgenics and the like) for the application of biological processes to the production of materials of use in medicine, foods, nutrition and industry. The term "nutraceutical" is defined as any substance that is a food or a part of a food and provides medical or health benefits, including the prevention and treatment of disease. The term "vitamin" is defined as any of various organic substances or compounds that are essential for the normal processes of growth and maintenance (e.g., essential for energy transformation and regulation of metabolism) of the body which are present in natural foodstuffs or sometimes produced within the body. The term "dietary supplement" is defined as any product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for supplementing the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract or combination of any ingredient described in (A), (B), (C), (D), or (E) hereinabove. If desired, excipients may also be introduced into one or more of the receiving chambers of the multi-compartment capsules of the present invention in addition to the active ingredient(s). For example, in some cases involving medicaments with poor water solubility, it may be desirable to

stabilize the liquids, solids or dispersions using a lipid, lipid, lecithin, ghee or the like. Still further by example, in some cases involving active ingredients or medicaments with poor bioavailability, bioequivalence, or other undesirable pharmaceutical properties (e.g., poor water solubility, pH lability, physical incompatibility, chemical incompatibility, macromolecular size and the like) such as proteins (e.g., hormones, erythropoietins, colony stimulating factors, interferons, interleukins, plasminogen activators, monoclonal antibodies, vaccines, plant proteins, such as soy and other therapeutic proteins) or other non-polar or weak-polar materials, it may be desirable to complement the active ingredient or medicament in liquid, solid or dispersion form using a fat, lipid, lipid, lecithin, ghee, polymers, viral and bacterial vectors and the like.

It may be demonstrated that as medical and pharmacy knowledge has continued to expand exponentially, new medicaments, new classes of medicaments and new delivery technologies are becoming available for use in animals and humans who experience particular medical diseases, illnesses or conditions. A disease, illness, or condition may affect one or more organ systems in an animal or human. Organ systems may include, for example: (1) autonomic, (2) cardiovascular, (3) neurological, (4) gastro-intestinal, (5) respiratory, (6) renal system, (7) psychiatric, (8) endocrine, (9) gynecologic, (10) urologic, (11) immunologic, (12) bone and joint systems, (13) ear, nose, and throat, (14) dermatologic, (15) hematologic, (16) infectious defense and (17) nutrition and metabolism. In an animal or human who may be suffering from one disease, illness or condition, it is common to also be suffering from a disease, illness or condition affecting one or more of the other organ system(s). These concomitant diseases, illnesses or conditions occurring within a single animal or human are often labeled as "co-morbidities," a term often shortened and referred to as "co-morbid."

New medicaments and delivery technologies are providing patients and their health care practitioners with unprecedented therapeutic options in managing diseases, illnesses and conditions. In spite of this sophistication, there has been no effort to develop new methods of using fixed combinations of medicaments for therapy of co-morbid diseases, illnesses or conditions. Moreover, there has been no effort to develop new methods of using fixed combinations of medicaments for management of a single disease, illness or condition affecting one or more organ system(s). The aforementioned fixed combinations may include a plurality of medicaments, which may be newly discovered and developed, or have been known for sometime or some combination of medicaments thereof. In any regard, said fixed combinations have not previously been contemplated in the art.

The following examples will illustrate the invention in further detail. It will be readily understood that the various active ingredients or medicaments that may be introduced into the receiving chambers of the multi-compartment capsules of the present invention, as generally described and illustrated in the Examples herein, are to be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or process for implementing those principles. Thus, the following more detailed description of the presently preferred embodiments of the methods, formulations, and compositions of the present invention, as represented in Examples I-XIV below, is not intended to limit the scope of the invention, as claimed, but is merely representative of presently preferred embodiments of the invention.

47

## Example I

Glucosamine/Chondroitin (Solid) & Vitamin E  
(Liquid)

As appreciated by those skilled in the art, arthritis is an inflammatory condition typically affecting the synovia membranes and cartilage of joints. It has been estimated that as many as one in three persons may experience symptoms associated with arthritis during their lifetime.

In addition to arthritis, various other chronic, debilitating conditions may afflict the aged. Many of these conditions result from the natural process of aging in humans. The natural aging process is partially due to the accumulation and effects of toxic free-radical chemicals. Free-radicals result from several homeostatic biochemical processes. It is, accordingly, desirable to develop nutraceutical or dietary supplement products which may alleviate multiple chronic, debilitating conditions. It is also desirable to package and administer such products in the most economic and convenient possible fashion.

The administration of glucosamine, a naturally occurring substance in mucopoly-saccharides, mucoproteins and chitin, is believed to promote the production of cartilage components and the repair of damaged cartilage. Clinical findings support that fibroblast cells increased production of mucopolysaccharide and collagen synthesis when glucosamine was added.

Chondroitin sulfates are large polymers of glycosaminoglycans, primarily D-glucuronic acid and D-acetylgalactosamine, and disaccharides and may be derived from the cartilage of bovine trachea. The administration of chondroitin sulfate has been shown to promote the formation of new cartilage matrix. In particular, chondroitin stimulates the metabolism of chondrocyte cells and the production of collagen and proteoglycan.

Vitamin E, also known as alpha-tocopherol, is a well-known scavenger of free-radicals in the body. Free-radical scavengers are sometimes referred to as anti-oxidants. This scavenging process is important for detoxifying the body of chemicals which are known to promote apoptosis, or programmed cell death. Apoptosis is a scientific description of cellular destruction. Although vitamin E is a popular anti-oxidant, it is poorly soluble in water and thus can be administered only as a liquid-oil formulation or in an oil formulation enclosed in a soft elastic capsule.

In one presently preferred embodiment of the present invention, therapeutically effective amounts of glucosamine, chondroitin, and vitamin E (active ingredients) may be introduced into receiving chambers of a multi-compartment capsule wherein at least two of the active ingredients have physical states (e.g., solid, liquid, gas or dispersion) that differ. Consistent with the foregoing, multi-compartment, multi-phase capsules and encapsulation technology are herein contemplated to produce a delivery vehicle for delivering anti-arthritis and anti-oxidant compounds to the body in a single dosage. A capsular format of the present invention may include the following composition:

## Primary Capsule:

Glucosamine HCl [500-2000 mg/day]	500 mg
--------------------------------------	--------

48

-continued

Chondroitin sulfate [400-1600 mg/day] Secondary Capsule:	400 mg
Vitamin E [200-400 IU/day]	200 IU

The incorporation of time-release coatings to varying the release rates of the active ingredients (e.g., glucosamine HCl/chondroitin sulfate and vitamin E) in the primary and secondary capsules, respectively, of the multi-compartment capsule may be used to target key time intervals or events when the body may be most able to utilize the named active ingredients. Thus, the incorporation of time-release coatings in the encapsulation process when forming a multi-compartment capsule may be specifically designed to fit the needs and desires of numerous different users having similar conditions that are being targeted for treatment.

A therapeutically effective amount of glucosamine HCl/chondroitin sulfate may be introduced into at least a portion of the internal periphery of the receiving chambers of a primary capsule in the form of a solid and a therapeutically effective amount of vitamin E may be introduced into at least a portion of a secondary capsule in the form of a liquid, if desired. Since the encapsulation process and multi-compartment, multi-phase capsule of the present invention are configured to apply to an anticipated treatment regime or medicinal design of a single dosage capsule, it will be readily appreciated that the introduction of one or more active ingredients into the receiving chambers of the primary and secondary capsules, respectively, is anticipated such that the various ingredients may be introduced in different receiving chambers to accommodate different treatment modalities. For example, a multi-compartment capsule may be formulated having glucosamine HCl and chondroitin sulfate introduced into the receiving chambers of the secondary capsule and vitamin E may be introduced into the receiving chamber of the primary capsule. It is intended, therefore, that the examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or method for implementing those principles.

## Example II

S-Adenosylmethione (SAME) (Solid) & Vitamin E  
(Liquid)

S-adenosylmethione (SAME), may be derived from two materials: methionine, a sulfur-containing amino acid, and adenosine triphosphate (ATP), the body's main energy compound. SAME was originally developed around 1950 as an antidepressant. Over the years, it has also been found that SAME may assist in alleviating arthritic symptoms, assist in the manufacture of melatonin, which is needed to regulate sleep, help protect DNA from harmful mutations and prevent certain types of nerve damage.

As noted above, vitamin E is a popular anti-oxidant, but it is poorly soluble in water and therefore can be administered only as a liquid-oil formulation. Vitamin E is typically measured in international units (IU) of alpha tocopherol.

In one presently preferred embodiment of the present invention, therapeutically effective amounts of SAME and vitamin E (active ingredients) may be introduced into receiving chambers of a multi-compartment capsule wherein SAME comprises a physical state (e.g. solid, liquid, gas or dispersion) different from the physical state of vitamin E. As shown in FIGS. 3 and 4, a therapeutically effective amount of SAME may be introduced into receiving chamber 218a and a thera-

peutically effective amount of vitamin E may be introduced into receiving chamber **218b** of a multi-compartment capsule **210** of the present invention. Consistent with the foregoing, multi-compartment, multi-phase capsules and encapsulation technology are herein contemplated to produce a delivery vehicle for delivering mood enhancing, anti-arthritis and anti-oxidant compounds to the body in a single dosage. A capsular format of the present invention may include the following composition:

Receiving Chamber (218a):	
S-adenosylmethione [200-1600 mg/day]	1000 mg
Receiving Chamber (218b):	
Vitamin E [200-400 IU/day]	200 IU

The incorporation of time-release coatings to varying the release rates of the active ingredients (e.g., SAME and vitamin E) of the multi-compartment capsule **210** may be used to target key time intervals or events when the body may be most able to utilize the named active ingredients. Thus, the incorporation of time-release coatings in the encapsulation process when forming a multi-compartment capsule may be specifically designed to fit the needs and desires of numerous different users having similar conditions that are being targeted for treatment.

According to one presently preferred embodiment of the present invention, a therapeutically effective amount of SAME may be introduced into at least a portion of the receiving chamber **218a** in the form of a solid and a therapeutically effective amount of vitamin E may be introduced into at least a portion of the receiving chamber **218b** of the primary capsule **211** in the form of a liquid.

In an alternative presently preferred embodiment of the present invention, therapeutically effective amounts of SAME and vitamin E (active ingredients) may be introduced into receiving chambers of a multi-compartment capsule wherein SAME comprises a physical state (e.g., solid, liquid, gas or dispersion) different from the physical state of vitamin E. As shown in FIG. 2, a therapeutically effective amount of SAME, in the form of a solid, may be introduced into receiving chamber **118** and **138** and a therapeutically effective amount of vitamin E, in the form of a liquid, may be introduced into receiving chamber **128** of a multi-compartment capsule **110** of the present invention. The material forming the primary capsule shell **111** may be formulated in a manner allowing for immediate dissolution and release of the contents of receiving chamber **118**. The material forming the secondary capsule shell **120** may be formulated in a manner allowing for either an immediate dissolution or a time-delayed dissolution and release of the contents of receiving chamber **128**. The material forming the tertiary capsule shell **138** may be formulated in a manner allowing for time-delayed dissolution and release of the contents of receiving chamber **138**. In this presently preferred embodiment of the present invention, a total daily dosage of SAME may be delivered as two separate dosages within a single oral dosage form. One presently preferred embodiment of the present invention thus makes for a more convenient dosage form.

Since the encapsulation process and multi-compartment, multi-phase capsule of the present invention are configured to apply to an anticipated treatment regime or medicinal design of a single dosage capsule, it will be readily appreciated that the introduction of one or more active ingredients into receiv-

ing chambers defined within a capsule is anticipated such that the various ingredients may be introduced in different receiving chambers to accommodate different treatment modalities. It is intended, therefore, that the examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or method for implementing those principles.

### Example III

#### Curcumin, Holy Basil, Zinc (Solid) & Fish Oil (Omega 3 Fatty Acids DHA & EPA-Liquid)

Curcumin belong to a class of compounds derived from the turmeric root and is a yellow-orange volatile oil. It is believed that curcumin has an inhibitory effect on carcinogenesis, which is the evolution of a normal cell into a cancerous cell. There is clinical evidence to suggest curcumin may help to prevent stomach, colon, oral, esophageal, breast and skin cancers. Additional studies have been conducted to show that curcumin may be helpful in balancing cholesterol levels, protecting against ulcers by inhibition of gastric acid secretion and protection of gastric mucosal tissue, and anti-inflammatory actions. In one clinical study, curcumin was found to be as effective as non-steroidal anti-inflammatory drugs in the treatment of arthritis and post-operative pain.

The administration of Holy Basil (*Ocimum sanctum*) has been shown to have an effect on promoting peripherally mediated analgesic effects. This action allows a broad range of therapeutic effects, including, anti-inflammatory, hypoglycemia, analgesic, anti-ulcer and anti-septic properties.

As known, zinc is a mineral that occurs in animal and plant tissues and is an important co-factor for various enzyme reactions in the body, as well as being helpful for the reproduction system, and for the manufacture of body proteins. Zinc is also an antioxidant nutrient, similar to vitamin E. There is clinical data that suggests that zinc may be important to the prostate and other reproductive organs in the body, may help in the contractility of muscles, help stabilize blood, help maintain the body's alkaline balance and aid in the digestion and metabolism of phosphorus.

Over several decades considerable evidence has been collected to suggest that fish and fish oils are beneficial to the heart, mental health and in reducing cancer risk. The "active" components of fish oils are eicosapentaenoic acid (EPA), a polyunsaturated fatty acid with a 20 carbon chain, and docosahexaenoic acid (DHA), a polyunsaturated fatty acid with a 22 carbon chain. Both active components are members of the omega-3 group of essential fatty acids and are found exclusively in marine animals. The best sources for EPA and DHA may be fatty fish such as herring, sardines, salmon and fresh tuna.

The recommended daily intake of EPA plus DHA is between 650 to 1000 mg/day. Clinical trials have used anywhere from 1 g/day to 10 g/day, but little additional benefit has been observed at levels above 5 g/day of EPA and DHA combined. The onset of beneficial effects is variable. Effects on cholesterol may occur in just a few weeks, but it may take there (3) months or longer to see effects in degenerative diseases, such as arthritis.

In one presently preferred embodiment of the present invention, therapeutically effective amounts of curcumin, Holy Basil, zinc and fish oil (active ingredients) may be introduced into receiving chambers of a multi-compartment capsule wherein curcumin, Holy Basil and zinc comprise a physical state (e.g. solid, liquid, gas or dispersion) different from the physical state of the fish oil. As shown in FIG. 2, a

51

therapeutically effective amount of curcumin may be introduced into receiving chamber 138 of a tertiary capsule 130, a therapeutically effective amount of Holy Basil and zinc may be introduced into receiving chamber 128 of a secondary capsule and a therapeutically effective amount of fish oil may be introduced into receiving chamber 118 of a primary capsule 111 of a multi-compartment capsule 110 of the present invention. Consistent with the foregoing, multi-compartment, multi-phase capsules and encapsulation technology are herein contemplated to produce a delivery vehicle for delivering anti-neoplastic, anti-inflammatory, analgesic and anti-oxidant compounds to the body in a single dosage. A capsular format of the present invention may include the following composition:

<u>Tertiary Capsule (130):</u>	
Curcumin [1200-1800 mg/day; 400 mg three times daily]	400 mg
<u>Secondary Capsule: (120):</u>	
Holy Basil [2.5 grams fresh dried leaf powder/day]	2.5 gms
Zinc [4-15 mg/day]	15 mg
<u>Primary Capsule (111):</u>	
Fish oil (Omega 3 fatty acids-DHA & EPA) [650-1000 mg/day]	1000 mg

The incorporation of time-release coatings to varying the release rates of the active ingredients (e.g., curcumin, Holy Basil, Zinc and fish oil) in the primary, secondary and tertiary capsules 111, 120, 130 of one presently preferred embodiment of a multi-compartment capsule 110 may be used to target key time intervals or events when the body may be most able to utilize the named active ingredients. Thus, the incorporation of time-release coatings in the encapsulation process when forming a multi-compartment capsule may be specifically designed to fit the needs and desires of numerous different users having similar conditions that are being targeted for treatment.

As contemplated herein, a therapeutically effective amount of curcumin may be introduced into at least a portion of the receiving chamber 138 of the tertiary capsule 130 in the form of a solid, a therapeutically effective amount of Holy Basil and zinc may be introduced into at least a portion of the receiving chamber 128 of the secondary capsule 120 in the form of a solid and a therapeutically effective amount of fish oil may be introduced into at least a portion of the primary capsule 111 in the form of a liquid. Since the encapsulation process and multi-compartment, multi-phase capsule of the present invention are configured to apply to an anticipated treatment regime or medicinal design of a single dosage capsule, it will be readily appreciated that the introduction of one or more active ingredients into the receiving chambers of the primary and secondary capsules, respectively, is anticipated such that the various ingredients may be introduced in different receiving chambers to accommodate different treatment modalities. It is intended, therefore, that the examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or method for implementing those principles.

Example IV

Vitamin C (Solid) & Vitamin E (Liquid)

It is believed that vitamin C plays an important role as a component of enzymes involved in the synthesis of collagen

52

and carnitine. A vital role of vitamin C, however, is believed to be that of the primary, water-soluble antioxidant in the human body. A daily intake of 6-1000 mg of vitamin C may be adequate for preventive purposes, but far larger quantities may be required to have an effect on halting or reversing cancer and heart disease.

As noted above, vitamin E is a popular anti-oxidant, but it is poorly soluble in water and therefore can be administered only as a liquid-oil formulation.

In one presently preferred embodiment of the present invention, therapeutically effective amounts of vitamin C and vitamin E (active ingredients) may be introduced into receiving chambers of a multi-compartment capsule wherein vitamin C comprises a physical state (e.g., solid, liquid, gas or dispersion) different from the physical state of vitamin E. Consistent with the foregoing, multi-compartment, multi-phase capsules and encapsulation technology are contemplated herein to produce a delivery vehicle for delivering anti-oxidant compounds to the body in a single dosage. A capsular format of the present invention may include the following composition:

<u>Primary Capsule:</u>	
Vitamin C [60-1000 mg/day]	500 mg
<u>Secondary Capsule:</u>	
Vitamin E [200-400 IU/day]	200 IU

The incorporation of time-release coatings to varying the release rates of the active ingredients (e.g., vitamin C and vitamin E) in different receiving chambers of a multi-compartment capsule may be used to target key time intervals or events when the body may be most able to utilize the named active ingredients. Thus, the incorporation of time-release coatings in the encapsulation process when forming a multi-compartment capsule may be specifically designed to fit the needs and desires of numerous different users having similar conditions that are being targeted for treatment and is contemplated herein.

A therapeutically effective amount of vitamin C may be introduced into at least a portion of a first receiving chamber in the form of a solid and a therapeutically effective amount of vitamin E may be introduced into at least a portion of a second receiving chamber in the form of a liquid. Since the encapsulation process and multi-compartment, multi-phase capsule of the present invention are configured to apply to an anticipated treatment regime or medicinal design of a single dosage capsule, it will be readily appreciated that the introduction of one or more active ingredients into the receiving chambers of the primary and secondary capsules, respectively, is anticipated such that the various ingredients may be introduced in different receiving chambers to accommodate different treatment modalities. It is intended, therefore, that the examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or method for implementing those principles.

Example V

Selenium/Vitamin C (Solid) & Vitamin E/Beta-Carotene/Fish Oil (Omega 3 Fatty Acids DHA & EPA) (Liquid)

Selenium is an essential trace mineral in the human body and an important part of antioxidant enzymes that protect

cells against the effects of free radicals that are produced during normal oxygen metabolism. As readily known in the art, the body has developed defenses, such as antioxidants, to assist in controlling levels of free radicals which can cause damage to cells and contribute to the development of some chronic diseases. It is also believed that Selenium is essential for normal functioning of the immune system and thyroid gland. The recommended dietary allowance for selenium is 55 mcg/day.

As noted above, it is believed that vitamin C plays an important role as a component of enzymes involved in the synthesis of collagen and carnitine and a vital role as a water soluble antioxidant in the human body. Vitamin E is another important anti-oxidant.

Beta-carotene is a substance found in plants that the body converts into vitamin A. It is believed that beta-carotene acts as an antioxidant and an immune system booster. There is no RDA for beta-carotene. The most common beta-carotene supplement intake is about 25,000 IU (15 mg) per day, however supplementation with as much as 100,000 IU (60 mg) per day has been reported.

It has been suggested that fish and fish oils are beneficial to the heart, mental health and in reducing cancer risk. The recommended daily intake of EPA plus DHA (the active components of fish oil) is between 650 to 1000 mg/day. Clinical trials have used anywhere from 1 g/day to 10 g/day, but little additional benefit has been observed at levels above 5 g/day of EPA and DHA combined.

In one presently preferred embodiment of the present invention, therapeutically effective amounts of selenium, vitamin C, beta-carotene, vitamin E and fish oil (active ingredients) may be introduced into receiving chambers of a multi-compartment capsule wherein selenium and vitamin C comprise a physical state (e.g., solid, liquid, gas or dispersion) different from the physical state of vitamin E, beta-carotene and fish oil (omega 3 fatty acids DHA & EPA). Specifically, a therapeutically effective amount of selenium and vitamin C may be introduced into one or more receiving chambers of a primary capsule and a therapeutically effective amount of vitamin E, beta-carotene and fish oil (omega 3 fatty acids DHA & EPA) may be introduced into one or more receiving chambers of a secondary capsule to form a multi-compartment capsule of the present invention. Consistent with the foregoing, multi-compartment, multi-phase capsules and encapsulation technology are herein contemplated to produce a delivery vehicle for delivering anti-oxidant compounds to the body in a single dosage. A capsular format of the present invention may include the following composition:

<u>Primary Capsule:</u>	
Selenium [50-100 mcg/day]	50 mcg
Vitamin C [60-1000 mg/day]	500 mg
<u>Secondary Capsule:</u>	
Beta-carotene [30-300 mg/day]	50 mg
Vitamin E [200-400 IU/day]	200 IU
Fish oil (Omega 3 fatty acids-DHA & EPA) [650-1000 mg/day]	1000 mg

The incorporation of time-release coatings to varying the release rates of the active ingredients (e.g., selenium, vitamin C, vitamin E, beta carotene and fish oil) in different receiving

chambers of a multi-compartment capsule may be used to target key time intervals or events when the body may be most able to utilize the named active ingredients. Thus, the incorporation of time-release coatings in the encapsulation process when forming a multi-compartment capsule may be specifically designed to fit the needs and desires of numerous different users having similar conditions that are being targeted for treatment and is contemplated herein.

A therapeutically effective amount of selenium and vitamin C may be introduced into one or more receiving chambers of a primary capsule in solid form and a therapeutically effective amount of vitamin E, beta carotene and fish oil may be introduced into one or more receiving chambers of a secondary capsule in the form of a liquid. Since the encapsulation process and multi-compartment, multi-phase capsule of the present invention are configured to apply to an anticipated treatment regime or medicinal design of a single dosage capsule, it will be readily appreciated that the introduction of one or more active ingredients into the receiving chambers of the primary and secondary capsules, respectively, is anticipated such that the various ingredients may be introduced in different receiving chambers to accommodate different treatment modalities. It is intended, therefore, that the examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or method for implementing those principles.

#### Example VI

##### Fluoxetine (Solid), S-Adenosylmethione (SAME) (Solid) & Vitamin E (Liquid)

As appreciated by those skilled in the art, depression is a mental state characterized by excessive sadness. Depression is one of several forms of mood disorders. Activity in those affected with depression may be agitated and restless or slow and retarded. Those affected may also show pessimistic or despairing behavior and may have disturbances in sleep, appetite and concentration. Depression is often a co-morbid condition with other chronic disease states involving the neurological system, cardiovascular system, respiratory system, endocrine system, musculoskeletal system, immune system, genitourinary system and the like. This list is should not be considered exclusive.

Administration of Fluoxetine is known by those of skill in the art to alleviate the signs and symptoms of depression. Fluoxetine belongs to a class of compounds which are given the functional name: selective serotonin reuptake inhibitors (SSRI's). This class may include, for example: fluoxetine (PROZAC®), sertraline (ZOLOFT®), paroxetine (PAXIL®), fluvoxamine (LUVOX®), citalopram (CELEXA®) and escitalopram (LEXAPRO®). As appreciated, the foregoing list is provided herein as exemplary and should not be considered exclusive or exhaustive.

Fluoxetine is a bicyclic compound, similar in structure to phenylpropanolamine. Fluoxetine structure imparts a high selectivity for interaction with cells of the nervous system for the function of preventing the reuptake of serotonin into pre-synaptic cell storage sites. This action leads to marked increases in synaptic concentration of serotonin and is facilitative of numerous physiological processes requiring serotonin neurotransmission. In the pharmaceutical field Fluoxetine is available as a hydrochloride salt (HCl).

S-adenosylmethione (SAME), is derived from two materials: methionine, a sulfur-containing amino acid, and adenosine triphosphate (ATP), the body's main energy compound. SAME was originally developed around 1950 as an antide-

pressant, but it was also found to be helpful in the alleviation of arthritic symptoms. SAME is essential for the manufacture of melatonin, which is needed to regulate sleep. It also helps to protect DNA from harmful mutations and may help prevent certain types of nerve damage. Current clinical research is beginning to confirm these antidepressant qualities of SAME.

Vitamin E, also named alpha-tocopherol, is a well-known scavenger of free-radicals in the body. Free-radical scavengers are sometimes referred to as anti-oxidants. This scavenging process is important for detoxifying the body of chemicals which are known to promote apoptosis, or programmed cell death. Apoptosis is a scientific description of cellular destruction. Although it is a popular anti-oxidant, Vitamin E is poorly soluble in water and thus can be administered only as a liquid-oil formulation or in an oil formulation enclosed in a soft elastic capsule. Vitamin E is typically measured in international units (IU) of alpha tocopherol.

In one presently preferred embodiment of the present invention, therapeutically effective amounts of Fluoxetine, SAME and Vitamin E (active ingredients) may be introduced into receiving chambers of a multi-compartment capsule wherein Fluoxetine and SAME comprises a physical state (e.g., solid, liquid, gas or dispersion) different from the physical state of Vitamin E. As shown in FIGS. 3 and 4, a therapeutically effective amount of Fluoxetine and SAME may be introduced into receiving chamber **218a** and a therapeutically effective amount of Vitamin E may be introduced into receiving chamber **218b** of a multi-compartment capsule **210** of the present invention. Consistent with the foregoing, multi-compartment, multi-phase capsules and encapsulation technology are herein contemplated to produce a delivery vehicle for delivering mood enhancing, anti-depressant and anti-oxidant compounds to the body in a single dosage. A capsular format of the present invention may include the following composition:

Receiving Chamber (218a):	
Fluoxetine [20-60 mg/day]	20 mg
S-adenosylmethione [200-1600 mg/day]	1000 mg
Receiving Chamber (218b):	
Vitamin E [200-400 IU/day]	200 IU

The incorporation of time-release coatings to varying the release rates of the active ingredients (e.g., Fluoxetine/SAME and Vitamin E) in the primary and secondary capsules, respectively, of the multi-compartment capsule may be used to target key time intervals or events when the body may be most able to utilize the named active ingredients. Thus, the incorporation of time-release coatings in the encapsulation process when forming a multi-compartment capsule may be specifically designed to fit the needs and desires of numerous different users having similar conditions that are being targeted for treatment.

According to one presently preferred embodiment of the present invention, a therapeutically effective amount of Fluoxetine and SAME may be introduced into at least a portion of the receiving chamber **218a** in the form of a solid and a therapeutically effective amount of Vitamin E may be introduced into at least a portion of the receiving chamber **218b** of the primary capsule **211** in the form of a liquid.

In an alternative presently preferred embodiment of the present invention, therapeutically effective amounts of Flu-

oxetine and SAME and Vitamin E (active ingredients) may be introduced into receiving chambers of a multi-compartment capsule wherein Fluoxetine and SAME comprises a physical state (e.g., solid, liquid, gas or dispersion) different from the physical state of Vitamin E. As shown in FIG. 2, a therapeutically effective amount of Fluoxetine and SAME, in the form of a solid, may be introduced into receiving chamber **118** and **138** and a therapeutically effective amount of Vitamin E, in the form of a liquid, may be introduced into receiving chamber **128** of a multi-compartment capsule **110** of the present invention. The material forming the primary capsule shell **111** may be formulated in a manner allowing for immediate dissolution and release of the contents of receiving chamber **118**. The material forming the secondary capsule shell **120** may be formulated in a manner allowing for either an immediate dissolution or a time-delayed dissolution and release of the contents of receiving chamber **128**. The material forming the tertiary capsule shell **138** may be formulated in a manner allowing for time-delayed dissolution and release of the contents of receiving chamber **138**. In this presently preferred embodiment of the present invention, a total daily dosage of Fluoxetine and SAME may be delivered as two separate dosages within a single oral dosage form. One presently preferred embodiment of the present invention thus makes for a more convenient dosage form.

Since the encapsulation process and multi-compartment, multi-phase capsule of the present invention are configured to apply to an anticipated treatment regime or medicinal design of a single dosage capsule, it will be readily appreciated that the introduction of one or more active ingredients into the receiving chambers of the primary and secondary capsules, respectively, is anticipated such that the various ingredients may be introduced in different receiving chambers to accommodate different treatment modalities. For example, a multi-compartment capsule may be formulated having Fluoxetine and SAME introduced into the receiving chambers of the secondary capsule and Vitamin E may be introduced into the receiving chamber of the primary capsule. It is intended, therefore, that the examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or method for implementing those principles.

#### Example VII

##### Rofecoxib (Solid) & Vitamin E (Liquid)

As appreciated by those skilled in the art, arthritis is an inflammatory condition typically affecting the synovia and cartilage of joints. It has been estimated that as many as one in three persons may experience symptoms associated with arthritis during their lifetime.

In addition to arthritis, various other chronic, debilitating conditions may afflict the aged. Many of these conditions result from the natural process of aging in humans. The natural aging process is partially due to the accumulation and effects of toxic free-radical chemicals. Free-radicals result from several homeostatic biochemical processes. It is, accordingly, desirable to develop pharmaceutical, biotechnical, nutraceutical or dietary supplement products which may alleviate multiple chronic, debilitating conditions. It is also desirable to package and administer such products in the most economic and convenient possible fashion.

Anti-inflammatory agents may have many diverse therapeutic roles in the human body. Inflammation is the process undertaken by the body as it responds to an injury. A typical inflammatory response involves blood vessel dilation,

increased blood flow to the site of injury, and influx of white blood cells to process and remove dead tissue. Inflammation can lead to pain and swelling at the site of injury. Medicaments used in modulating the inflammatory response may be divided into steroid and non-steroidal labels. The latter is more commonly identified as non-steroidal anti-inflammatory drugs (NSAIDs).

Rofecoxib belongs to a class of NSAID compounds given the functional name cyclo-oxygenase-2 ("COX-2") inhibitors. This class may include, for example: rofecoxib (VIOXX®), celecoxib (CELEBREX®), valdecoxib (BEXTRA®), and meloxicam (MOBIC®). As appreciated, the foregoing list is provided herein as exemplary and should not be considered exclusive or exhaustive.

Rofecoxib is presently believed to inhibit the action of COX-2, an enzyme involved in the production of prostaglandins in the human body. Prostaglandins serve many diverse roles, one of which is to stimulate an inflammation mechanism in immune responses. Recently, Rofecoxib was labeled for use in the treatment of osteoarthritis, rheumatoid arthritis, acute pain, and primary dysmenorrhea.

Vitamin E, also named alpha-tocopherol, is a well-known scavenger of free-radicals in the body. Free-radical scavengers are sometimes referred to as anti-oxidants. This scavenging process is important for detoxifying the body of chemicals which are known to promote apoptosis, or programmed cell death. Apoptosis is a scientific description of cellular destruction. Although it is a popular anti-oxidant, Vitamin E is poorly soluble in water and thus can be administered only as a liquid-oil formulation or in an oil formulation enclosed in a soft elastic capsule.

In one presently preferred embodiment of the present invention, therapeutically effective amounts of Rofecoxib and Vitamin E (active ingredients) may be introduced into receiving chambers of a multi-compartment capsule wherein Rofecoxib comprises a physical state (e.g., solid, liquid, gas or dispersion) different from the physical state of Vitamin E. As shown in FIGS. 3 and 4, a therapeutically effective amount of Rofecoxib may be introduced into receiving chamber 218a and a therapeutically effective amount of Vitamin E may be introduced into receiving chamber 218b of a multi-compartment capsule 210 of the present invention. Consistent with the foregoing, multi-compartment, multi-phase capsules and encapsulation technology are herein contemplated to produce a delivery vehicle for delivering anti-inflammatory and anti-oxidant compounds to the body in a single dosage. A capsular format of the present invention may include the following composition:

Receiving Chamber (218a):	
Rofecoxib [12.5-25 mg/day]	25 mg
Receiving Chamber (218b):	
Vitamin E [200-400 IU/day]	200 IU

The incorporation of time-release coatings to varying the release rates of the active ingredients (e.g., Rofecoxib and Vitamin E) of the multi-compartment capsule 210 may be used to target key time intervals or events when the body may be most able to utilize the named active ingredients. Thus, the incorporation of time-release coatings in the encapsulation process when forming a multi-compartment capsule may be

specifically designed to fit the needs and desires of numerous different users having similar conditions that are being targeted for treatment.

According to one presently preferred embodiment of the present invention, a therapeutically effective amount of Rofecoxib may be introduced into at least a portion of the receiving chamber 218a in the form of a solid and a therapeutically effective amount of Vitamin E may be introduced into at least a portion of the receiving chamber 218b of the primary capsule 211 in the form of a liquid.

In an alternative presently preferred embodiment of the present invention, therapeutically effective amounts of Rofecoxib and Vitamin E (active ingredients) may be introduced into receiving chambers of a multi-compartment capsule wherein Rofecoxib comprises a physical state (e.g., solid, liquid, gas or dispersion) different from the physical state of Vitamin E. As shown in FIG. 2, a therapeutically effective amount of Rofecoxib, in the form of a solid, may be introduced into receiving chamber 118 and 138 and a therapeutically effective amount of Vitamin E, in the form of a liquid, may be introduced into receiving chamber 128 of a multi-compartment capsule 110 of the present invention. The material forming the primary capsule shell 111 may be formulated in a manner allowing for immediate dissolution and release of the contents of receiving chamber 118. The material forming the secondary capsule shell 120 may be formulated in a manner allowing for either an immediate dissolution or a time-delayed dissolution and release of the contents of receiving chamber 128. The material forming the tertiary capsule shell 138 may be formulated in a manner allowing for time-delayed dissolution and release of the contents of receiving chamber 138. In this presently preferred embodiment of the present invention, a total daily dosage of Rofecoxib may be delivered as two separate dosages within a single oral dosage form. One presently preferred embodiment of the present invention thus makes for a more convenient dosage form.

Since the encapsulation process and multi-compartment, multi-phase capsule of the present invention are configured to apply to an anticipated treatment regime or medicinal design of a single dosage capsule, it will be readily appreciated that the introduction of one or more active ingredients into receiving chambers defined within a capsule is anticipated such that the various ingredients may be introduced in different receiving chambers to accommodate different treatment modalities. It is intended, therefore, that the examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or method for implementing those principles.

#### Example VIII

##### Diphenhydramine Hydrochloride (Solid) & Vitamin E (Liquid)

As appreciated by those skilled in the art, allergic reactions are conditions wherein the immune system is stimulated to identify, segregate and dispose of exogenous chemicals which cannot be recognized by the body. Allergic reactions are often associated with the release of histamine, a chemical compound which produces changes in the permeability of blood vessels and the accumulation of other immune system cells. In some circumstances, it may be desirable to modulate the amount of allergic response that is capable of being generated by the immune system.

Diphenhydramine belongs to a class of compounds which are given the functional name: histamine-1 (H<sub>1</sub>) receptor antagonists. These compounds are more generally labeled as

antihistamines. These antagonists are further divided according to their chemical structures. Diphenhydramine is an ethanolamine (aminoalkyl ether) derivative. Other chemical divisions may include, for example: ethylenediamine, propylamine, phenothiazine, piperazine. The ethanolamine division may include, for example: diphenhydramine, clemastine, dimenhydrinate, and doxylamine. As appreciated, the foregoing list is provided herein as exemplary and should not be considered exclusive or exhaustive.

Antihistamines block the interaction of the neurotransmitter, histamine, with H<sub>1</sub> receptors located in smooth muscle linings of the gastrointestinal tract, bronchial tract and large blood vessels. This blocking action may lead to marked relaxation in smooth muscle tone and is facilitative of numerous physiological processes including respiration.

The H<sub>1</sub> antagonists may also be divided according to their selectivity for central and peripheral H1 receptors. A second-generation of H<sub>1</sub> has emerged in recent years. These agents have a greater selectivity for peripheral H<sub>1</sub> receptors. Second-generation H<sub>1</sub> receptor antagonists may include, for example: azelastine (ASTELLN®), cetirizine (ZYRTEC®), desloratadine (CLARINEX®), fexofenadine (ALLEGRA®) and loratadine (CLARITIN®).

Vitamin E, also named alpha-tocopherol, is a well-known scavenger of free-radicals in the body. Free-radical scavengers are sometimes referred to as anti-oxidants. This scavenging process is important for detoxifying the body of chemicals which are known to promote apoptosis, or programmed cell death. Apoptosis is a scientific description of cellular destruction. Although it is a popular anti-oxidant, Vitamin E is poorly soluble in water and thus can be administered only as a liquid-oil formulation or in an oil formulation enclosed in a soft elastic capsule.

In one presently preferred embodiment of the present invention, therapeutically effective amounts of Diphenhydramine and Vitamin E (active ingredients) may be introduced into receiving chambers of a multi-compartment capsule wherein at least two of the active ingredients have physical states (e.g., solid, liquid, gas or dispersion) that differ. Consistent with the foregoing, multi-compartment, multi-phase capsules and encapsulation technology are herein contemplated to produce a delivery vehicle for delivering anti-allergic and anti-oxidant compounds to the body in a single dosage. A capsular format of the present invention may include the following composition:

Primary Capsule:	
Diphenhydramine HCl [25-100 mg/day]	50 mg
Secondary Capsule:	
Vitamin E [200-400 IU/day]	200 IU

The incorporation of time-release coatings to varying the release rates of the active ingredients (e.g., Diphenhydramine and Vitamin E) in the primary and secondary capsules, respectively, of the multi-compartment capsule may be used to target key time intervals or events when the body may be most able to utilize the named active ingredients. Thus, the incorporation of time-release coatings in the encapsulation process when forming a multi-compartment capsule may be specifically designed to fit the needs and desires of numerous different users having similar conditions that are being targeted for treatment.

A therapeutically effective amount of Diphenhydramine may be introduced into at least a portion of the internal periphery of the receiving chambers of a primary capsule in the form of a solid and a therapeutically effective amount of Vitamin E may be introduced into at least a portion of a secondary capsule in the form of a liquid, if desired. Since the encapsulation process and multi-compartment, multi-phase capsule of the present invention are configured to apply to an anticipated treatment regime or medicinal design of a single dosage capsule, it will be readily appreciated that the introduction of one or more active ingredients into the receiving chambers of the primary and secondary capsules, respectively, is anticipated such that the various ingredients may be introduced in different receiving chambers to accommodate different treatment modalities. For example, a multi-compartment capsule may be formulated having Diphenhydramine introduced into the receiving chambers of the secondary capsule and Vitamin E may be introduced into the receiving chamber of the primary capsule. It is intended, therefore, that the examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or method for implementing those principles.

#### Example IX

##### Celecoxib (Solid) & Ibuprofen (Liquid)

As appreciated by those skilled in the art, arthritis is an inflammatory condition typically affecting the synovia and cartilage of joints. It has been estimated that as many as one in three persons may experience symptoms associated with arthritis during their lifetime.

Anti-inflammatory agents may have many diverse therapeutic roles in the human body. Inflammation is the process undertaken by the body as it responds to an injury. A typical inflammatory response involves blood vessel dilation, increased blood flow to the site of injury, and influx of white blood cells to process and remove dead tissue. Inflammation can lead to pain and swelling at the site of injury. Medicaments used in modulating the inflammatory response may be divided into steroid and non-steroidal labels. The latter is more commonly identified as non-steroidal anti-inflammatory drugs (NSAIDs).

Celecoxib belongs to a class of NSAID compounds given the functional name cyclo-oxygenase-2 ("COX-2") inhibitors. This class may include, for example: rofecoxib (VIOXX®), celecoxib (CELEBREX®), valdecoxib (BEXTRA®), etodolac (LODINE®) and meloxicam (MOBIC®). As appreciated, the foregoing list is provided herein as exemplary and should not be considered exclusive or exhaustive.

Celecoxib is believed to inhibit the action of COX-2, an enzyme involved in the production of prostaglandins in the human body. Prostaglandins serve many diverse roles, one of which is to stimulate an inflammation mechanism in immune responses. Recently, Celecoxib was labeled by the United States Food and Drug Administration (FDA) for use in the treatment of osteoarthritis, rheumatoid arthritis, acute pain, and primary dysmenorrhea.

Ibuprofen is another NSAID and is believed to function as a non-selective inhibitor of cyclo-oxygenase. Ibuprofen has been labeled by the FDA for use in the treatment of osteoarthritis, rheumatoid arthritis, relief of mild to moderate pain and primary dysmenorrhea. Ibuprofen belongs to a class of compounds called phenyl-a-methylacetic acids, which are derived from salicylic acid. Non-selective cyclo-oxygenase inhibitors may include, for example: ibuprofen (MOTRIN®),

61

naproxen (NAPROSYN®), diclofenac (VOLTAREN®), flurbiprofen (ANSAID®), indomethacin (INDOCIN®), ketoprofen (ORUDIS®), ketorolac (TORADOL®), nabumetone (RELAFEN®), oxaprozom (DAYPRO®), piroxicam (FELDENE®) and sulindac (CLINORIL®). As appreciated, the foregoing list is provided herein as exemplary and should not be considered exclusive or exhaustive.

In one presently preferred embodiment of the present invention, therapeutically effective amounts of Celecoxib and Ibuprofen (active ingredients) may be introduced into receiving chambers of a multi-compartment capsule wherein Celecoxib comprises a physical state (e.g., solid, liquid, gas or dispersion) different from the physical state of Ibuprofen. As shown in FIGS. 3 and 4, a therapeutically effective amount of Celecoxib may be introduced into receiving chamber 218a and a therapeutically effective amount of Ibuprofen may be introduced into receiving chamber 218b of a multi-compartment capsule 210 of the present invention. Consistent with the foregoing, multi-compartment, multi-phase capsules and encapsulation technology are herein contemplated to produce a delivery vehicle for delivering anti-arthritis and anti-oxidant compounds to the body in a single dosage. A capsular format of the present invention may include the following composition:

<u>Receiving Chamber (218a):</u>	
Celecoxib [200-400 mg/day]	200 mg
<u>Receiving Chamber (218b):</u>	
Ibuprofen [2400-3200 mg/day]	800 mg

The incorporation of time-release coatings to varying the release rates of the active ingredients (e.g., Celecoxib and Ibuprofen) of the multi-compartment capsule 210 may be used to target key time intervals or events when the body may be most able to utilize the named active ingredients. Thus, the incorporation of time-release coatings in the encapsulation process when forming a multi-compartment capsule may be specifically designed to fit the needs and desires of numerous different users having similar conditions that are being targeted for treatment.

According to one presently preferred embodiment of the present invention, a therapeutically effective amount of Celecoxib may be introduced into at least a portion of the receiving chamber 218a in the form of a solid and a therapeutically effective amount of Ibuprofen may be introduced into at least a portion of the receiving chamber 218b of the primary capsule 211 in the form of a liquid.

In an alternative presently preferred embodiment of the present invention, therapeutically effective amounts of Celecoxib and Ibuprofen (active ingredients) may be introduced into receiving chambers of a multi-compartment capsule wherein Celecoxib comprises a physical state (e.g., solid, liquid, gas or dispersion) different from the physical state of Ibuprofen. As shown in FIG. 2, a therapeutically effective amount of Celecoxib, in the form of a solid, may be introduced into receiving chamber 128 and a therapeutically effective amount of Ibuprofen, in the form of a liquid, may be introduced into receiving chambers 118 and 138 of a multi-compartment capsule 110 of the present invention.

The material forming the primary capsule shell 111 may be formulated in a manner allowing for immediate dissolution and release of the contents of receiving chamber 118. The material forming the secondary capsule shell 120 may be

62

formulated in a manner allowing for either an immediate dissolution or a time-delayed dissolution and release of the contents of receiving chamber 128. The material forming the tertiary capsule shell 138 may be formulated in a manner allowing for time-delayed dissolution and release of the contents of receiving chamber 138. In this presently preferred embodiment of the present invention, a total daily dosage of Ibuprofen may be delivered as two separate dosages within a single oral dosage form. One presently preferred embodiment of the present invention thus makes for a more convenient dosage form.

Since the encapsulation process and multi-compartment, multi-phase capsule of the present invention are configured to apply to an anticipated treatment regime or medicinal design of a single dosage capsule, it will be readily appreciated that the introduction of one or more active ingredients into receiving chambers defined within a capsule is anticipated such that the various ingredients may be introduced in different receiving chambers to accommodate different treatment modalities. It is intended, therefore, that the examples provided herein be viewed as exemplary of the principles of the present invention, and not as restrictive to a particular structure or method for implementing those principles.

Examples X

Some embodiments of the present invention will use of or more of the below ingredients in a multi-compartment capsule, combinable as would be recognized in view of the teachings of the present application in combination with the knowledge available to one of ordinary skill in the art. It is noted that the following non-limiting lists illustrate exemplary ingredients that can be used with the present invention, including the broader subclasses and classes to which they belong.

Botanicals
Green Tea
<i>Griffonia Simplicifolia</i>
Guarana
Guggul
<i>Gymnema Sylvestre</i>
Hawthorne
Henna
Herbal Extracts, Standardized
Herbal Teas
Hops
Horehound
Horse Chestnut
Horsetail
Hysop
Ipriflavone
Jojoba Oil
Juniper Berries
Kava Kava
Kelp Extract
Kola Nut
Kombucha
Kudzu
Larch
Lavender
Lemon Balm
Licorice Extract
Liden Flowers
Lobelia
Maca
Maitake Mushroom
Marshmallow
Milk Thistle
Molasses
Mushrooms
Neem

## 63

-continued

Botanicals	
Nettle	
Noni	5
Nopal	
Oatstraw	
Octacosanol	
Olive Extract	
Orange Peel Extract	
Oregano Oil	10
Oregon Mountain Grape	
Organic Sweeteners	
Parsley	
Passion Flower	
Pau d'Arco	
Pennyroyal	15
Peppermint	
Pfaffia Paniculata	
Pine Bark Extract	
Piper Longum	
<i>Pygeum Africanum</i>	
Quercetin	20
Raspberry Powder	
Red Clover	
Reishi Mushroom	
Resveratrol Extract	
Rhubarb Root	
Rice Products	25
Rose Hips	
Rosemary Extract	
Sage	
Sarsaparilla	
Saw Palmetto	
<i>Schizandra</i>	
Seaweed extracts	30
Senna	
Shatavari	
Shiitake Mushroom	
Silymarin	
Skullcap	
Slippery Elm	35
Soy Isoflavones	
Soybean Products	
<i>Spirulina</i>	
St. John's Wort	
Stevia	
Summa	40
Tea Tree Oil	
Terminalia Ajruna	
<i>Tribulus Terrestris</i>	
Triphala	
Tumeric	
Uva Ursi	
Valerian Extract	45
Vegetable Extracts	
Vitex	
Wheat Germ	
White Willow Bark	
Wild Cherry bark	
Wild Yam	50
Witch Hazel	
Wormwood	
Yarrow	
Yellow Dock	
Yerba Sante	
Yohimbine	55
Yucca	

## Extracts

20-ECD 7-9%	
4-Androstenedione 99%	
Acetyl L-Carnitine HCl 99%	
Adenophora Tetraohylla Ext 5:1	
Alisma Extract 10:1	65
Alpha Lipoic Acid 99%	

## 64

-continued

Extracts	
Angelica Root Extract	
Arbutin 99%	
Artemisia Extract 4:1	
Artichoke Extract 5%, Globe	
Asparagus Extract 4:1	
Asparagus Powder	
Astragalus Extract 10:1	
Astragalus Extract 4:1	
Astragalus Extract 5:1	
Astragalus Root Extract 0.5%	
Astragalus Root Powder	
Atractylodes Extract 10:1	
Avena Sativa Extract 10.1	
Avena Sativa Extract 4:1	
Barbed Skullcap Extract 10:1	
Barberry Extract 10%	
Bee Pollen Powder	
Beta-Sisterol 35%	
Bilberry Extract 10:1	
Bitter Melon Extract 8:1	
Black Cohosh Extract 2.5%	
Black Cohosh Root Powder	
Black Pepper Extract 4:1	
Black Soy Bean Extract 10.1	
Bone Powder	
Boswellia Serrata Extract 65%	
Broccoli Sprout Extract 10:1	
Buchu Leaf Powder	
Buplerum (Chai Hu) Extract 5:1	
Burdock Root Extract 4:1	
Cabbage Extract 4:1	
Caffeine (Natural) 86-87%	
Caffeine 99%	
Calcium Citrate Granular 21%	
Calcium-Pyruvate 99%	
Carrot Root Extract 4:1	
Cassia Nomame Extract 4:1	
Catnip Extract 4:1	
Cat's Claw (Inner Bark) Powder	
Cauliflower Extract 4:1	
Celandine (Greater) Extract 4:1	
Celery Seed Extract	
Cetyl Myristoleate 11%	
Cetyl Myristoleate 20%	
Chaenomeles Extract 4:1	
Chamomile Flower Extract 10:1	
Chamomile Flower Extract 4:1	
Chaste Tree Berry Extract 4:1	
Chitin	
Chitosan 80%	
Chitosan 90%	
Chondroitin Sulfate 90%	
Chrysin 99%	
Cinnamon Powder	
Cistanches Extract 5:1	
Citrus Aurantium Extract 6%	
Citrus Bioflavonoid Complex 13%	
Citrus Peel Extract 5:1	
Clove Extract 5:1	
Clove Powder	
Coca Extract 4:1	
Codonopsis Pilosula Extract 5:1	
Colostrum	
Common Peony Extract 8:1	
Cordyceps Extract 7%	
Cornsilk Extract 4:1	
Cornsilk Powder	
Corydalis Extract 10:1	
Cranberry Extract 4:1	
Cranberry Powder	
Curcumin Extract 95%	
Cuscuta Extract 5:1	
Damiana Extract 4:1	
Damiana Leaves Powder	
Dandelion Powder	
Dandelion Root Extract 6:1	
Danshen Extract 80%	

## US 9,241,911 B2

65

-continued

Extracts	
D-Calcium Pantothenate	
Devil's Claw Extract 2.5%	5
Devil's Claw Extract 4:1	
Devil's Claw Root Powder	
DHEA 99%	
Diosgenin 95%	
DL-Phenyl Alanine	
DMAE Bitartrate	10
Doug Quai Extract 10:1	
Doug Quai Extract 4:1	
Doug Quai Root Powder	
D-Ribose	
Echinacea Angustifolia Extract 4:1	
Echinacea Leaf Powder	15
Echinacea Purpurea Extract 10:1	
Echinacea Purpurea Extract 4%	
Echinacea Purpurea Extract 4:1	
Echinacea Purpurea Root Powder	
Elder Flower Extract 4:1	
Elderberry Extract 20:1	20
Elderberry Extract 4:1	
Epimedium Extract 10%	
Epimedium Extract 10:1	
Epimedium Extract 4:1	
Epimedium Extract 5%	
Epimedium Powder	
Eucommia (Du Thong) Extract 5:1	25
Fennel Seed Extract 4:1	
Fennel Seed Powder	
Fenugreek Extract 4:1	
Fenugreek Extract 6:1	
Feverfew Extract 5:1	
Fisetin	30
Fish Oil Powder	
Forbidden Palace Flower Extract 5:1	
Forskolin 8%	
Fo-Ti Extract 12:1	
Fo-Ti Extract 8:1	
Fo-Ti Powder	35
Gardenia Extract 8:1	
Garlic Extract. 4:1	
Garlic Powder	
Gentian Root Extract 6:1	
Ginger Extract 4:1	
Ginger Root Extract 5%	40
Ginger Root Powder	
Ginkgo Biloba Extract 8:1	
Ginkgo Extract 24/6%	
Ginkgo Extract 24/6% <5	
Ginkgo Extract 24/7%	
Ginkgo Leaf Extract 4:1	45
Ginkgo Leaf Powder	
Ginseng (Korean) Powder	
Ginseng (Panax) Extract 5%	
Ginseng (Panax) Extract 8%	
Ginseng (Panax) Extract 80%	
Glucosamine Konjac Powder	
Glucosamine HCl 95% Granulation	50
Glucosamine HCl 99%	
Glucosamine Sulfate Potassium	
Glucosamine Sulfate Sodium 95% Granulation	
Glucosamine Sulfate Sodium 99%	
Goldenrod Extract 4:1	55
Goldenrod Powder	
Goldenseal Root Extract 14%	
Goldenseal Root Powder	
Gotu Kola Extract 16%	
Gotu Kola Extract 4:1	
Gotu Kola Extract 8:1	60
Gotu Kola Powder	
Grape Fruit Powder	
Grape Seed	
Grape Seed Extract 10:1	
Grape Seed Extract 20:1	
Grape Seed Extract 4:1	65
Grape Seed Extract 5:1	

66

-continued

Extracts	
Grape Seed Extract 95%	
Grape Seed Powder	
Grape Skin Extract 20:1	
Grape Skin Extract 4:1	
Grass-Leaved Sweetflai Extract	
Green Lip Mussel Extract	
Green Tea Extract 30%	
Green Tea Extract 4:1	
Green Tea Extract 95%	
Guarana Seed Extract 10%	
Guarana Seed Extract 22%	
Guarana Seed Extract 25%	
Guggul Extract 10%	
Guggul Extract 2.5%	
Gugulipid Extract 10%	
Gymnema Sylvestre Extract 25%	
Gymnema Sylvestre Powder	
Hawthorne Berry Extract 4:1	
Hawthorne Berry Powder	
Hawthorne Leaf Extract 2%	
Hearbacious Peony Extract 5:1	
Hesperidin Extract 98%	
Honeysuckle Herb Extract 4:1	
Hops Flower Extract 4:1	
Horehound Extract 10:1	
Horehound Extract 4:1	
Horehound Herb Powder	
Horse Chestnut Extract 20%	
Horse Chestnut Extract 4:1	
Horse Chestnut Powder	
Horsetail Extract 7%	
Horsetail Powder.	
Houttuynia Cordata Extract 5:1	
Hydrangea Extract 8:1	
Hydroxy Apatite	
Hyssop Extract 4:1	
Indole-3-Carbino199%	
Isodon Glaucoalyx Extract 10:1	
Japanese Knotweed Extract	
Jiaogulan Extract 4:1	
Jin Qian Cao Extract 4:1	
Jingjie Extract 4:1	
Jujube Fruits Extract 4:1	
Kava Kava Extract 30%	
Kava Kava Powder	
Kelp Extract 4:1	
Kelp Powder	
Kidney Bean Extract 10:1	
Kidney Bean Pole 4:1	
Kidney Bean Pole 8:1	
Kidney Bean Powder	
Kola Nut Extract 10%	
Kudzu Extract 4:1	
Kudzu Extract 6:1	
Lettuce Extract 4:1	
L-Glutamine	
L-Glycine	
Licorice Extract 10%	
Licorice Extract 5:1	
Licorice Powder	
Lotus Leaf Powder	
L-Tyrosine	
Lycium Fruit Extract 4:1	
Lycium Fruit Extract 5:1	
Ma Huang Extract 6%	
Ma Huang Extract 8%	
Maca Extract 0.6%	
Maca Extract 4:1	
Maca Root Powder	
Magnesium Stearate	
Magnolia Bark Powder	
Magnolia Officinal Extract 4:1	
Maitike Mushroom Extract 4:1	
Marigold Extract (Lutein 5%)	
Methoxyisoflavone 99%	
Methylsulfonylmethane 99%	
Milk Thistle Extract 4:1	

67

-continued

Extracts	
Milk Thistle Seed Extract 80% silymarin	5
Morinda Extract 5:1	
Motherwort Extract 4:1	
Motherwort Powder	
Mucuna Pruriens Extract (115% L-Dopa)	
Muira Puama Extract 12:1	
Muira Puama Extract 4:1	10
Muira Puama Powder	
Mushroom Extract 10:1 (feishi)	
Mustard Seed Extract 8:1	
Myrobalan Extract 4:1	
Myrrha Gum Extract 2.5%	
N-Acetyl-D-Glucosamine	15
N-Acetyl-L-Cysteine	
Nettle Extract 7%	
Nettle Leaf Extract 4:1	
Nettle Leaf Powder	
Noni Powder	
Olive Leaf Extract 18%	20
Olive Powder	
Orange Peel Extract 4:1	
Orange Peel Powder	
Oroxylum Indicum Extract 4:1	
Oroxylum Indicum Powder	
Oyster Meat Powder	25
Oyster Shell Powder	
Papaya Fruit Extract 4:1	
Parsley Extract 10:1	
Parsley Extract 4:1	
Parsley Leaf Extract 4:1	
Parsley Powder	
Passion Flower Extract 4:1	30
Passion Flower Powder	
Pau D'Arco Powder	
Peppermint Extract 4:1	
Peppermint Powder	
Perilla Seed Extract 4:1	
Periwinkle Extract 4:1	35
Pharbitidis Extract 4:1	
Phosphatidyl Serine 20%	
Pine Bark Extract 4:1	
Plantago Asiatica Leaf Extract 5:1	
Polygala Tenoifolia Extract 4:1	
Polygonum Extract	40
Polygonum Extract 4:1	
Pregnenolone 99%	
Propolis Extract 3%	
Pseudoginseng Extract	
Psyllium extract 4:1	
Pumpkin Seed Extract 4:1	45
Purple Willow Bark Extract 4:1	
Purslane Herb Extract 4:1	
Pygeum Extract 4:1	
Quercetin	
Radish Extract 4:1	
Radix Isatidis Extract 4:1	50
Radix Polygoni Extract 4:1	
Red Clover Extract 4:1	
Red Pepper Extract 4:1	
Red Yeast Rice	
Red Yeast Rice Extract 10:1	
Red Yeast Rice Powder	
Rehmannia Root Extract 4:1	55
Reishi Mushroom Extract 4:1	
Rhodiola Rosea Extract 4:1	
Rhododendron Extract 4:1	
Rhododendron Powder	
Rhubarb Extract 4:1	
Rhubarb Root Powder	60
Riboflavin (B2)	
Rice Powder	
Rosemary Extract 20%	
Rumex Madaid Extract 4:1	
Salvia Extract 10:1	
Salvia Extract 4:1	65
SAMe	

68

-continued

Extracts	
Saw Palmetto Extract 25%	
Saw Palmetto Extract 25%	
Saw Palmetto Extract 25%	
Saw Palmetto Extract 4:1	
Saw Palmetto Extract 45-50%	
Saw Palmetto Oil 85-95%	
Saw Palmetto Powder	
Schizandra Extract 10:1	
Schizandra Extract 4:1	
Scopolia Acutangula Powder	
Sea Cucumber Powder	
Senna Leaf Powder	
Sesame (Black) Seed Powder	
Shark Cartilage Powder	
Shitake Mushroom Extract	
Siberian Ginseng Extract 0.8%	
Siberian Ginseng Extract 4:1	
Siberian Ginseng Powder	
Skullcap Extract 4:1	
Skullcap Extract 4:1	
Slippery Elm Powder	
Sodium-Pyruvate 99%	
Songaria Cynomorium Extract 4:1	
Songaricum Powder	
Spirulina Powder	
St. John's Wort Extract 03%	
St. John's Wort Extract 4:1	
St. John's Wort Powder	
Stanol 50%	
Stephania Extract 4:1	
Stevia Extract 4:1	
Sulfate N+	
Suma Root Extract 4:1	
Suma Root Powder	
Taurine Powder	
Thorowax Extract 4:1	
Tomato Extract	
Tomato Extract (0.2% Lycopene)	
(trans)-Resveratrol 20-25%	
Tribulus Extract 10:1	
Tribulus Extract 40%	
Tribulus Powder	
Trifal Extract 4:1	
Turmeric Extract 4:1	
Turmeric Root Powder	
Uva Ursi Extract 4:1	
Uva Ursi Powder	
Valerian Root Extract 0.8%	
Valerian Root Extract 4:1	
Valerian Root Powder	
Vinca Major Seed Extract 10:1	
White Wax Extract 4:1	
White Willow Bark 15% (total salicins )	
White Willow Bark 20%	
White Willow Bark 25%	
White Willow Bark Extract 4:1	
White Willow Bark Powder	
Wild Yam Extract 10:1	
Wild Yam Extract 16%	
Wild Yam Extract 4:1	
Wild Yam Extract 6%	
Wild Yam Powder	
Williams Elder Extract 4:1	
Wolfberry Fruit Extract 10:1	
Wolfiporia Extract 8:1	
Yellow Dock Root Extract 4:1	
Yerba Mate Extract (2% caffeine)	
Yerba Mate Extract 4:1	
Yohimbe Bark Extract 15:1	
Yohimbe Bark Extract 2%	
Yohimbe Bark Extract 3%	
Yohimbe Bark Powder	
Yucca Extract 4:1	

69		70	
Enzymes		Herbal Oils	
Alpha Galactosidase		Artichoke Oil	
Amylase		Black Currant Seed Oil 14% GLA	
Bromelain	5	Black Currant Seed Oil 15% GLA	
Cellulose		Borage Oil 20% GLA	
Papain		Borage Oil 22% GLA	
Peptidase		Boswellia Serrata Oil	
Protease		CLA Conjugated Linolic Acid 75% min.	
Proteolytic Enzymes		Evening Primrose Oil 10% GLA	
Superoxide Dismutase	10	Evening Primrose Oil 9% GLA	
Trypsin		Flax Seed Oil 50% ALA	
Phospholipids		Garlic Oil	
Lecithin	15	Grape Seed Oil	
Phosphatidyl Choline		Guggul Lipid Oil	
Phosphatidyl Serine		Olive Leaf Extract	
Specialty Nutraceuticals		Oregano Oil	
5-Hydroxytryptophan		Perilla Oil 60% ALA	
Acetyl L-Carnitine	25	Pumpkin Seed Oil	
Alpha Lipoic Acid		Pygeum Oil	
Alpha-Ketoglutarates		Rosehip Oil	
Bee Products		Rosemary Oil	
Betaine Hydrochloride		Saw Palmetto Oil	
Bovine Cartilage		Sterols	
Caffeine	30	Tocotrienol Palm Oil	
Cetyl Myristoleate		Walnut Oil	
Charcoal		Wheat Germ Oil	
Chitosan		Sesame Seed Oil	
Choline		Dill Seed Oil	
Chondroitin Sulfate		Clove Bud Oil	
Coenzyme Q10		Ginger Root Oil	
Collagen	35	Cinnamon Leaf Oil	
Colostrum		Fennel Seed Oil	
Creatine		Curcuma Longa Oil	
Cyanocobalamin (Vitamin B12)		Cummin Seed Oil	
DMAE		Celery Seed Oil	
Fumaric Acid		Coriander Seed Oil	
Germanium Sesquioxide	40	Red Raspberry Seed Oil	
Glandular Products		Cranberry Seed Oil	
Glucosamine HCL		Blackberry Seed Oil	
Glucosamine Sulfate		Marine Oils	
HMB (Hydroxyl Methyl Butyrate)		Cod Liver Oil (1000 A/100 D)	Cod Liver Oil (2500A/250D)
Immunoglobulin (Immune System Support)		Fish Oil 30% EPA/20% DHA	Fish oil Concentrated
Lactic Acid	45	Fish Oil Deodorized	Marine Lipid Oil 18/12
L-Carnitine		Marine Lipid Oil 30/20	Marine Lipid Oil 36/24
Liver Products		Salmon Oil 18% EPA/12% DHA	Squalene Oil (Shark)
Malic Acid		Other Oils	
Maltose-anhydrous		Alpha Lipoic Acid	
Mannose (d-mannose)		Cetyl Myristoleate CM	
MSM	50	Coenzyme Q10	
Other Carnitine Products		Lecithin	
Phytosterols		Medium Chain Triglycerides MCT.	
Picolinic Acid		Vitamins	
Pyruvate		Ascorbic Acid (Vitamin C)	
Red Yeast Extract		B Vitamins	
SAME	55	Biotin	
Selenium Yeast		Fat Soluble Vitamins	
Shark Cartilage		Folic Acid	
Theobromine		HCA (Hydroxycitric Acid)	
Vanadyl Sulfate		Inositol	
Velvet Deer Antler		Mineral Ascorbates	
Yeast	60	Mixed Tocopherols	
Herbal Oils		Niacin (Vitamin B3)	
Aloe Vera	65		
Artichoke Oil			

71

-continued

Vitamins	
Orotic Acid	5
PABA (Para-Aminobenzoic Acid)	
Pantothenates	
Pantothenic Acid (Vitamin B5)	
Pyridoxine Hydrochloride (Vitamin B6)	
Riboflavin (Vitamin B2)	
Synthetic Vitamins	
Thiamine (Vitamin B1)	
Tocotrienols	
Vitamin A	
Vitamin D	10
Vitamin E	
Vitamin F	
Vitamin K	
Vitamin Oils	
Vitamin Premixes	
Vitamin-Mineral Premixes	
Water Soluble Vitamins	

	20
--	----

Carotenoids	
Apocarotenal	25
Astaxanthin	
Beta-Carotene	
Canthaxanthin	
Carotenoids	
Lutein/Lutein Esters	
Lycopene	
Zeaxanthin	

	30
--	----

Hormones	
7-Keto-DHEA	35
Androstenedione	
DHEA	
Melatonin	
Nor-Androstenedione	
Progesterone	
Progesterone	
19 Nor-4-Androstendiol	
19 Nor-4-Androstenedione	
19 Nor-5-Androstenediol	
19 Nor-5-Androstenedione	40
3-Indolebutyric Acid	
4 Androstendiol	
4 Androstendione	
6 Furfurylaminopurine	
6-Benzylaminopurine	

	45
--	----

Minerals	
Boron	50
Calcium	
Chelated Minerals	
Chloride	
Chromium	
Coated Minerals	
Cobalt	
Copper	
Dolomite	
Iodine	
Iron	55
Magnesium	
Manganese	
Mineral Premixes	
Mineral Products	
Molybdenum	
Other Minerals	

72

-continued

Minerals	
Phosphorus	5
Potassium	
Selenium	
Sodium	
Specialty Minerals	
Trace Minerals	
Vanadium	
Zinc	
Malic Acid	
Pyruvate	

	15
--	----

Probiotics	
Acidophilus	20
Bifido Bacteria	
Lactobacillus	

	20
--	----

Proteins/Amino Acids	
Amino Acids	25
Betaine	
Casein	
Functional Soy	
Glutamic Acid	
L-Alanine	
L-Arginine	
L-Cysteine	
L-Glutamine	
L-Glycine	
L-Histidine	
L-Isoeucine	
L-Leucine	
L-Lysine	
L-Methionine	
L-Ornithine	
L-Phenylalaline	
L-Proline	
L-Taurine	
L-Threonine	
L-Tryptophan	
L-Tyrosine	
L-Valine	
N-Acetyl-L-Cysteine	
Protein	
Soluble Soy	
Soy Protein Isolates	
Textured Soy	
Whey Protein Isolates	

	30
--	----

Specialty Nutrients	50
ATP	
Forskolin	
Sterol Esters	
Stanol Esters	
Probiotics	
Lactoferrin	
Lutein Esters	
Zeaxanthin	
Immunoglobulins	
Ipriflavone	60
Isoflavones	
Fructo-Oligo-Saccharides	
Inulin	
Huperzine A	
Melatonin	
Medicinal Mushrooms	
Bile Products	

Peptone Products  
 Glandular Products  
 Pancreatic Products  
 Thyroid Products  
 Ribose  
 Probiotics  
 Oleo Resins  
 Dill Seed Oleo Resin  
 Black Pepper Oleoresin  
*Capsicum* Oleoresin

## Examples XI

The present invention further contemplates the use of any active ingredients or medicaments known in the art. In this regard, it is well within the purview of the skilled artisan to select a particular combination of active ingredients or medicaments. The following non-limiting lists illustrate exemplary active ingredients or medicaments and the broader subclasses and classes to which they belong for use in this invention.

## Medicaments Acting on the Autonomic Nervous System

## Adrenergic Medicaments

## Cholinergic Medicaments

## Direct Muscarinic Agonists Choline Esters

acetylcholine  
 bethanechol (URECHOLINE®)  
 carbachol  
 methacholine (PROVOCHOLINE®)

## Alkaloids

muscarine  
 pilocarpine (PILOCAR®)

## Direct Nicotinic Agonist

nicotine

## Acetylcholinesterase Inhibitors Acetylcholinesterase Inhibitors ("Reversible")

edrophonium (TENSILON®)  
 neostigmine (PROSTIGMIN®)  
 physostigmine (ANTILIRIUM®)

## Acetylcholinesterase Inhibitors ("Irreversible")

(diisopropylfluorophosphate DFP)  
 echothiophate (PHOSPHOLINE®)  
 isofluorophate (FLOROPRYL®)

## Muscarinic Antagonists Atropine

ipratropium (ATROVENT®)  
 pirenzepine  
 scopolamine

## 2-PAM: Acetylcholinesterase Reactivator Pralidoxime (Protopam) {2-PAM}: peripheral acetylcholinesterase reactivator for certain phosphoryl-enzyme complexes

## Ganglionic Blockers

hexamethonium  
 mecamylamine (INVERSINE®)  
 trimethaphan

## Catecholamines

dobutamine (DOBUTREX®)  
 dopamine (INTROPIN®)  
 epinephrine  
 isoproterenol (ISUPREL®)  
 norepinephrine (LEVOPHED®)

## Direct Adrenoceptor Agonist Medicaments

albuterol (VENTOLIN®, PROVERITIL®)  
 clonidine (CATAPRES®)  
 methoxamine (VASOXYL®)  
 oxymetazone (AFRIN®)  
 phenylephrine (NEO-SYNEPHRINE®)  
 ritodrine (YUTOPAR®)

salmeterol (SEREVENT®)

terbutaline (BRETHINE®)

## Indirect-Acting Sympathomimetic Medicaments

amphetamine

5 cocaine

ephedrine, Pseudoephedrine tyramine

## Alpha-Adrenoceptor Antagonists Medicaments

doxazosin (Cardura CARDURA®)

10 labetalol (TRANDATE®, NORMODYNE®)

phenoxybenzamine (DIBENZYLINE®)

phentolamine (REGITINE®)

prazosin (MINIPRESS®)

terazosin (HYTRIN®)

15 tolazoline (PRISCOLINE®)

trimazosin

yohimbine (YOCON®)

## β-Adrenoceptor antagonist Medicaments

atenolol (TENORMIN®)

20 butoxamine

esmolol (BREVIBLOC®)

labetalol (TRANDATE®, NORMODYNE®)

metoprolol (LOPRESSOR®)

nadolol (CORGARD®)

25 pindolol (VISKEN®)

propranolol (INDERAL®)

timolol (BLOCADREN®)

## Adrenergic Neuron Blocking Medicaments

gutanethidine (ISMELIN®)

30 reserpinme

## Cardiovascular System Disorders

## Cardiovascular testing and diagnosis

## Hypertension (HTN)

## Heart Failure

35 Ischemic Heart Disease

## Myocardial Infarction

## Arrhythmias

## Isolated Diastolic Heart Failure and Cardiomyopathies

## Cardiac Transplantation

40 Venous Thromboembolism

## Stroke

## Hyperlipidemia

## Peripheral vascular disease

## Diuretics

45 carbonic-anhydrase inhibitors

loop diuretics

osmotic diuretics

potassium sparing diuretics

thiazide diuretics

50 Antiarrhythmic Medicaments

## Sodium Channel blocking agents

isopyramide (NORPACE®)

flecainide (TAMBOCOR®)

ibutilide

55 lidocaine (XYLOCAINE®)

mexiletine (MEXITIL®)

morizine (ETHMOZINE®)

procainamide (PRONESTYL®, PROCAN®)

propafenone (RYTHMOL®)

60 quinidine

tocainide (TONOCARD®)

## Calcium Channel blocking agents

bepidil (VASOCOR®)

diltiazem (CARDIZEM®)

65 verapamil (ISOPTIN®, CALAN®)

## Adrenergic receptor antagonists

propranolol (INDERAL®)

Other medicaments  
 adenosine (ADENOCARD®)  
 amiodarone (CORDARONE®)  
 bretylium (BRETLYLOL®)  
 disopyramide (NORPACE®)  
 esmolol (BREVIBLOC®)  
 sotalol (BETAPACE®)

Hypolipidemic medicaments  
 HMG CoA Reductase Inhibitors  
 atorvastatin (LIPITOR®)  
 cerivastatin (BAYCOL®)  
 lovastatin (MEVACOR®)  
 pravastatin (PRAVOCHOL®)  
 simvastatin (ZOCOR®)

Bile-acid sequestrants  
 cholestyramine (QUESTRAN®)  
 colestipol (COLESTID®)

Fibric acids  
 clofibrate  
 fenofibrate (TRICOR®)  
 gemfibrozil (LOPID®)  
 niacin, nicotinic acid  
 probucol (LORELCO®)

Antihypertensive medicaments  
 Adrenergic receptor antagonists  
 acebutalol (SECTRAL®)  
 atenolol (TENORMIN®)  
 betaxolol (BETOPTIC®)  
 bisoprolol (ZEBETA®)  
 carteolol (CARTROL®)  
 clonidine (CATAPRES®)  
 labetalol (NORMODYNE®)  
 metoprolol (TOPROL®)  
 penbutalol (LEVATOL®)  
 pindolol (VISKEN®)  
 prazosin (MINIPRES®)  
 propranolol (INDERAL®)  
 terazosin (HYTRIN®)  
 timolol (TIMOPTIC®)

Calcium Channel Antagonists  
 amlodipine (NORVASC®)  
 diltiazem (CARDIZEM®)  
 felodipine (Plendil)  
 isradipine (DYNACIRC®)  
 nicardipine (CARDENE®)  
 nifedipine (PROCARDIA®)  
 nimodipine (NIMOTOP®)  
 nisoldipine (SULAR®)  
 verapamil (ISOPTIN®, CATAN®)

Angiotensin Converting Enzyme (ACE) Inhibitor  
 benazepril (LOTENSIN®)  
 bepridil (VASCOR®)  
 captopril (CAPOTEN®)  
 enalapril (VASOTEC®)  
 fosinopril (MONOPRIL®)  
 lisinopril (PRINIVIL®, ZESTRIL®)  
 moexipril (UNIVASC®)  
 quinapril (ACCUPRIL®)  
 ramipril (ALTACE®)

Angiotensin II Receptor Antagonists  
 losartan (COZAAR®)  
 valsartan (DIOVAN®)

Diuretics  
 amiloride (MIDAMOR®)  
 bumetanide (BUMEX®)  
 chlorothalidone (HYGROTON®)  
 ethacrynic acid (EDECRIN®)

furosemide (LASIX®)  
 hydrochlorothiazide (DIURIL®)  
 indapamide (LOZOL®)  
 metolazone (ZAROXOLYN®)  
 5 torsemide (DEMADEX®)  
 triamterene

Other Agents  
 hydralazine (APRESOLINE®)  
 minoxidil (ROGAINE®)  
 10 nitroprusside (NIPRIDE®)  
 prazosin (MINIPRES®)  
 reserpine  
 sotalol (BREVIBLOC®)  
 spironolactone (ALDACTONE®)  
 15 terazosin (HYTRIN®)

Antianginal Medicaments  
 Organic nitrates  
 Calcium Channel Antagonists  
 Adrenergic Receptor Antagonists  
 20 amyl nitrite  
 erythryl tetranitrate  
 isosorbide dinitrate (ISORDIL®)  
 nitroglycerin  
 pentaerythritol tetranitrate

25 Congestive Heart Failure Medicaments  
 phosphodiesterase (PDE) inhibitors  
 aminone (INOCOR®)  
 milrinone (PRIMACOR®)  
 carvedilol (COREG®)

30 cardiac glycosides  
 digitoxin  
 digoxin  
 diuretics  
 ACE Inhibitors  
 35 Dobutamine  
 dopamine

Respiratory System Disorders  
 Asthma  
 Chronic Obstructive Lung Disease (COLD)/Chronic  
 40 Obstructive Pulmonary Disease (COPD)  
 Acute Respiratory Distress Syndrome (ARDS)  
 Drug-Induced Pulmonary Disease  
 Cystic Fibrosis

Corticosteroids  
 45 beclomethasone  
 betamethasone  
 cortisone  
 dexamethasone  
 fluticasone (FLOVENT®/FLONASE®)  
 50 hydrocortisone  
 methylprednisolone  
 prednisolone  
 prednisone  
 triamcinolone

55 sympathomimetics  
 albuterol (PROVENTIL®/VENTOLIN®)  
 salmeterol (SEREVENT®)  
 muscarinic antagonists  
 ipratropium (COMBIVENT®)

60 leukotriene pathway inhibitors  
 montelukast (SINGULAIR®)  
 zafirtukast (ACCOLATE®)

mast cell stabilizers  
 cromolyn (INTAL®)

65 methylxanthines  
 theophylline  
 aminophylline

Dnase (Pulmozyme)  
 Gastrointestinal System Disorders  
 Gastro-esophageal Reflux Disease (GERD)  
 Peptic Ulcer Disease  
 Inflammatory Bowel Disease  
 Nausea and Vomiting  
 Diarrhea, Constipation, Irritable Bowel Disease (IBD)  
 Portal Hypertension and Cirrhosis  
 Drug-Induced Liver Disease  
 Pancreatitis  
 Viral Hepatitis  
 Liver Transplantation  
 Histamine-2 receptor antagonists  
   famotidine (PEPCID®)  
   nizatidine (AXID®)  
   pantoprazole (PROTONIX®)  
   rabeprazole (ACIPHEX®)  
   ranitidine (ZANTAC®)  
 Proton Pump Inhibitors (PPIs)  
   esomeprazole (NEXIUM®)  
   lansoprazole (PREVACID®)  
   omeprazole (PRILOSEC®)  
 Anti-nausea/anti-vertigo medicaments  
   anticholinergics  
   antihistamines (Histamine-1 receptor antagonists)  
   dopamine antagonists  
   prokinetic gastric stimulant  
   serotonin 5HT<sub>3</sub> receptor antagonists  
     dolasetron (ANZMET®)  
     granisetron (KYTRIL®)  
     ondansetron (ZOFTRAN®)  
   other medicaments  
   hydroxyzine (ATARAX®, VISTARIL®)  
   corticosteroids  
   benzodiazepines  
   cannabinoids  
 Prokinetic gastric stimulants (gastric motility stimulants)  
   cisapride (PROPULSID®)  
   metoclopramide (REGLAN®)  
   Laxatives  
   Saline laxatives  
   magnesium salts  
   sodium salts  
   irritant/stimulant medicaments  
   cascara  
   senna  
   phenolphthalein  
   bisacodyl  
   casanthranol  
   castor oil  
   bulk producing medicaments  
   methylcellulose  
   psyllium  
   polycarbophil  
   lubricant  
   mineral oil  
   surfactants  
   docusate  
   miscellaneous  
   glycerin  
   lactulose  
 Anti-diarrheal medicaments  
   diphenoxylate  
   atropine  
   diphenoxin  
   loperamide

  bismuth  
   *lactobacillus*  
 Ulcerative Colitis Medicaments  
   mesalamine  
 5   olsalazine  
 Renal System Disorders  
   Acute Renal Failure  
   Progressive Renal Failure/Chronic Renal Failure  
 Neurologic System Disorders  
 10   Multiple Sclerosis and inflammatory polyneuropathies  
   Epilepsy  
   Parkinson's disease and Movement Disorders  
   Pain management  
   Headache  
   Amyotrophic Lateral Sclerosis  
 15   Anti-epileptic medicaments  
   carbamazepine (TEGRETOL®)  
   divalproex sodium (DEPAKOTE®)  
   felbamate (Felbatol FELBATOL®)  
   gabapentin (NEURONTIN®)  
 20   lamotrigine (LAMICTAL®)  
   oxcarbazepine (TRILEPTAL®)  
   phenytoin (DILANTIN®)  
   topiramate (TOPAMAX®)  
   zonisamide (ZONEGRAN®)  
 25   Antimigraine medicaments  
   Serotonin 5HT<sub>1d</sub> receptor agonists  
   almotriptan (AXERT®)  
   frovatriptan (FROVA®)  
   naratriptan (AMERGE®)  
 30   rizatriptan (RIZALT®)  
   sumatriptan (IMITREX®)  
   zolmitriptan (ZOMIG®)  
   ergot alkaloids  
   dihydroergotamine (DHE®)  
 35   isometheptine/dichlorophenazone (MIDRIN®)  
   caffeine  
   pizotifen (SANOMIGRAN®)  
   Sedative-hypnotic Medicaments  
   benzodiazepines  
 40   alprazolam (XANAX®)  
   clonazepam (KLORIOPIIN®)  
   clorazepate (TRANXENE®)  
   diazepam (VALIUM®)  
   flumazenil (ROMAZICON®)-antagonist  
 45   lorazepam (ATIVAN®)  
   midazolam (VERSED®)  
   triazolam (HALCION®)  
   barbiturates/Anesthetics  
   pentobarbital (Nembutal)  
 50   Phenobarbital (Luminal LUMINAL®)  
   thiopental (PENTOTHAL®)  
   non-depressant anxiolytic  
   buspirone (BUSPAR®)  
   Treatment of Alcoholism  
 55   disulfiram (ANTABUSE®)  
   Pain Management Medicaments  
   Opioids  
   Opioid Peptides  
     beta-endorphin  
 60      dynorphin  
     enkephalins  
   Agonists  
   codeine  
   etorphine  
 65   fentanyl (SUBLIMAZE®)  
   hydrocodeine  
   hydromorphone

meperidine (DEMEROL®)  
 methadone (DOLOPHINE®)  
 morphine  
 oxycodone  
 propoxyphene  
 Agonist-antagonists  
   buprenorphine  
 Partial Agonist  
   dezocine (DALGAN®)  
   nalbuphine (NUBAIN®)  
   pentazocine (TALWAIN®)  
 Antagonist  
   naloxone (NARCAN®)  
 Non-opiate  
   acetaminophen (TYLENOL®)  
   tramadol (ULTRAM®)  
 Anti-Parkinsonism Medicaments  
 levodopa  
 carbidopa  
 bromocriptine (PARLODEL®)  
 pergolide (PERMAX®)  
 amantadine (SYMMETREL®)  
 selegiline (DEPRENYL®)  
 anticholinergic agents  
 dopamine Agonists  
   pramipexole (MIRAPEX®)  
   ropinirole (REQUIP®)  
 COMT inhibitors  
   entacapone (COMTAN®)  
   tolcapone (TASMAR®)  
 Anti-Spasticity Medicaments  
 baclofen (LIORESAL®)  
 botulinum toxin type A (BOTOX®)  
 carisoprodol (SOMA®, RELA®)  
 chlorphenesin (Maolate MAOLATE®)  
 chlorzoxazone (PARAFLEX®)  
 cyclobenzaprine (FLEXERIL®)  
 dantrolene (DANTRUM®)  
 diazepam (VALIUM®)  
 metaxalone (SKELAXIN®)  
 methocarbamol (ROBAXIN®)  
 orphenadrine (NOR-FLEX®)  
 tizanidine (ZANAFLEX®)  
 Psychiatric System Disorders  
   Childhood psychiatric disorders  
   Attention Deficit Hyperactivity Disorder (ADHD)/Attention Deficit Disorder (ADD)  
   Eating disorders  
   Alzheimer's disease and Dementia Disorders  
   Substance abuse and Addictive Disorders  
     alcohol, tobacco and caffeine abuse  
   Schizophrenia  
   Depressive disorders  
   Bipolar disorders  
   Anxiety disorders  
   Obsessive-Compulsive disorders  
   Sleep disorders  
   Psychostimulant Medicaments  
     amphetamine mixed salts (ADDERALL®)  
     dextroamphetamine (DEXEDRINE®)  
     methylphenidate (RITALIN®, CONCERTA®)  
   Antipsychotic Medicaments (dopamine antagonists)  
   Phenothiazine type  
     chlorpromazine (THORAZINE®)  
     fluphenazine (PROLIXIN®)  
   Thioxanthene type  
     thiothixene (NAVANE®)

Butyrophenone type  
   haloperidol (HALDOL®)  
 Dibenzodiazepine type  
   clozapine (CLOZARIL®)  
 5 Thienobenzodiazepine type  
   olanzapine (ZYPREXA®)  
   quetiapine (SEROQUEL®)  
 Antidepressant Medicaments  
 Tricyclic antidepressants (TCA's)  
 10 amitriptyline (EVAVIL®, ENDEP®)  
   clomipramine (ANAFRANIL®), also a SSRI  
   desipramine (Norpramin NORPRAMIN®)  
   doxepin (SINEQUAN®)  
   imipramine (TOFRANIL®)  
 15 maprotiline (LUDIOMIL®)  
   nortriptyline (AVENTYL®, PAMELOR®)  
   protriptyline (VIVACTIL®)  
 Monoamine oxidase inhibitors (MAO-I's)  
   clorgyline (specific for MAO type A)  
 20 isocarboxazid (MARPLAN®)  
   phenelzine (NARDIL®)  
   tranylcypromine (PARNATE®)  
 Second Generation Medicaments (not including SSRIs)  
   amoxapine (ASENDIN®)  
 25 bupropion (WELLBUTRIN®)  
   netazodone (SERZONE®)  
   trazodone (DESYREL®)  
 Serotonin-Specific Reuptake Inhibitors (SSRIs)  
   citalopram (CELEXA®)  
 30 clomipramine (ANAFRANIL®)  
   escitalopram (LEXAPRO®)  
   fluoxetine (PROZAC®)  
   fluvoxamine (LUVOX®)  
   paroxetine (PAXIL®)  
 35 sertraline (ZOLOFT®)  
 Other  
   lithium  
   mirtazapine (TEMERON®)  
   venlafaxine (EFFEXOR®)  
 40 Anti-Anxiety Agents  
   barbiturates  
   benzodiazepines  
   buspirone (BUSPAR®) chloral hydrate  
   doxepin  
 45 hydroxyzine  
   sedative-hypnotics  
   serotonin reuptake inhibitors  
 Anti-Demential Medicaments  
   cholinesterase inhibitors  
 50 donepezil (ARICEPT®)  
   galantamine (REMINYL®)  
   rivastigmine (EXELON®)  
   tacrine (COGNEX®)  
 Endocrinologic System Disorders  
 55 Diabetes mellitus  
   Thyroid disorders  
   Adrenal Gland disorders  
   Pituitary Gland disorders  
   ACTH  
 60 Adrenal androgens  
   Adrenocortical Function Antagonists  
   Mineralocorticoid antagonists  
   Anti-Diabetic Medicaments  
   Insulin  
 65 Sulfonylureas  
   acetoexamide (DYMELOR®)  
   chlorpropamide (DIABINESE®)

## 81

glimepiride (AMARYL®)  
 glipizide (GLUCOTROL®)  
 glyburide (MICRONASE®, DIABETA®)  
 tolazamide (TOLINASE®)  
 tolbutamide (ORINASE®)  
 Biguanides  
 metformin (GLUCOPHAGE®)  
 Alpha-glucosidase Inhibitors  
 acarbose (PRECOSE®)  
 miglitol (GLYSET®)  
 Thiazolidinedione Derivatives  
 pioglitazone (ACTOS®)  
 rosiglitazone (AVANDIA®)  
 troglitazone (REZULIN®)  
 Thyroid Disorder Medicaments  
 Levothyroxine  
 Liothyronine  
 Liotrix  
 Hypothalamic and Pituitary Gland Medicaments  
 bromocriptine (PARLODEL®)  
 chorionic gonadotropin (hCG®)  
 corticotropin generic (ACTH®)  
 cosyntropin (CORTROSYN®)  
 desmopressin (DDAVP®)  
 gonadorelin acetate (GnRH) (LUTREPULSE®)  
 gonadorelin hydrochloride (GnRH) (FACTREL®)  
 goserelin acetate (ZOLADEX®)  
 growth hormone  
 histrelin (SUPPRELIN®)  
 leuprolide (LUPRON®)  
 menotropins (hMG) (PERGONAL®, HUMEGON®)  
 natarelin (SYNAREL®)  
 octreotide (SANDOSTATIN®)  
 oxytocin (PITOCINIT®, SYNTOCINON®)  
 pergolide (PERMAX®)  
 protirelin (THYPINONE®, RELEFACT TRH®)  
 sermorelin (GHRH) (GEREF®)  
 somatrem (PROTROPIN®)  
 somatropin (HUMATROPE®, NUTROPIN®)  
 thyrotropin (TSH) (THYTROPAR®)  
 urofollitropin (METRODIN®)  
 vasopressin (Pitressin Synthetic)  
 Gynecologic System and Obstetric Conditions  
 Pregnancy and Lactation  
 Infertility  
 Contraception  
 Menstruation-related disorders  
 Endometriosis  
 Hormone Replacement Therapy (HRT)  
 Conjugated estrogens (PREMARIN®)  
 desogestrel  
 di-norgestrel  
 ethinyl diacetate  
 ethinyl estradiol  
 levonorgestrel  
 medroxyprogesterone  
 norethindrone norgestimate  
 progesterone  
 Urologic System Disorders  
 Erectile Dysfunction  
 Benign Prostatic Hypertrophy  
 Urinary Incontinence  
 apomorphine  
 alprostadit  
 phosphodiesterase (PDE-5) inhibitors  
 sildenafil (VIAGRA®)  
 tadalafil (CIALIS®)

## 82

vardenafil (LEVITRA®)  
 tolterodine (DETROL®)  
 tamulosin (FLOMAX®)  
 yohimbine  
 5 Immunologic System Disorders  
 Systemic Lupus Erythematosus and other Collagen-vascular diseases  
 Allergic and pseudo-allergic drug reactions  
 Bone and Joint System Disorders  
 10 Osteoporosis and Osteomalacia  
 Rheumatoid Arthritis  
 Osteoarthritis  
 Gout and hyperuricemia  
 Medicaments used in the Control of Inflammation  
 15 Non-steroidal anti-inflammatory drugs (NSAIDs)  
 aspirin  
 diclofenac (CATAFLAM®, VOLTAREN®)  
 diflunisal (DOLOBID®)  
 etodolac (LODINE®)  
 20 fenoprofen (NALFON®)  
 flubiprofen (ANSAID®)  
 ibuprofen (MOTRIN®, ADVIL®, NUPRIN®)  
 indomethacin (INDOCIN®)  
 ketoprofen (ORUDIS®)  
 25 ketorolac (TORADOL®)  
 meclofenamate  
 nabumetone (RELAFEN®)  
 naproxen (NAPROSYN®)  
 oxaprozin (DAYPRO®)  
 30 phenylbutazone  
 piroxicam (FELDENE®)  
 salicylate  
 sulindac (CLINORIL®)  
 tolmetin (TOLECTIN®)  
 35 Cyclooxygenase-2 inhibitors (COX-2)  
 celecoxib (CELEBREX®)  
 rofecoxib (VIOXX®)  
 Arthritis and Gout Medicaments  
 allopurinol  
 40 anti-malarial compounds  
 chloroquine  
 colchicine  
 enbrel  
 Glucocorticoids  
 45 Gold  
 methotrexate  
 NSAIDs  
 Penicillamine  
 Other Medicaments  
 50 alendronate (FOSAMAX®)  
 raloxifene (EVISTA®)  
 Disorders of the Eyes, Ears, Nose, and Throat Systems  
 Glaucoma  
 Allergic rhinitis  
 55 Histamine-1 receptor antagonists  
 brompheniramine (DIMETANE®)  
 cetirizine (ZYRTEC®)  
 chlorpheniramine (CHLOR-TRIMETON®)  
 clemastine (TAVIST®)  
 60 cyproheptadine (PERIACTIN®)  
 dimenhydrinate (DRAMAMINE®)  
 diphenhydramine (BENDARYL®)  
 doxylamine (SOMNEX®, UNISOM®)  
 fexofenadine (ALLEGRA®)  
 65 loratidine (CLARITIN®)  
 Sympathomimetic medicaments  
 pseudoephedrine (Sudated)

Dermatologic System Disorders  
 Acne  
 Psoriasis  
 Rosacea and pigmentation disorders  
 Hematologic System Disorders 5  
 Hematopoiesis  
 Anemias  
 Coagulation disorders  
 Sickle-cell anemia  
 Drug-induced hematologic disorders 10  
 Coagulation Disorders Medicaments  
 aspirin  
 clopidogrel (PLAVIX®)  
 fibrinolytic inhibitors  
 fibrinolytics 15  
 glycoprotein (GP) IIb/IIIa antagonists/monoclonal anti-  
 bodies  
 abciximab (REOPRO®)  
 eptifibatid (INTEGRELIN®)  
 tirofiban (AGGRASTAT®) 20  
 heparin  
 low-molecular weight heparins  
 Plasma fractions-blood factors  
 ticlopidine (TICLID®) 25  
 vitamin K  
 warfarin (COUMADIN®)  
 Infectious System Diseases  
 Central Nervous System (CNS) infections  
 Lower Respiratory Tract Infections 30  
 Upper Respiratory Tract Infections  
 Skin and Soft Tissue Infections  
 Infective Endocarditis  
 Tuberculosis  
 Gastrointestinal Infections and Enterotoxigenic poison-  
 ings 35  
 Intra-abdominal Infections  
 Parasitic diseases  
 Urinary Tract Infections and Prostatitis 40  
 Sexually Transmitted Diseases  
 Bone and Joint Infections  
 Sepsis and Septic Shock  
 Superficial Fungal Infections  
 Invasive Fungal Infections 45  
 Infections in Immunocompromised Patients  
 Antimicrobial prophylaxis in Surgery  
 Vaccines, toxoids, and other immunobiologics  
 Human Immunodeficiency Virus Infection  
 Medicaments Used in Infectious Diseases 50  
 Cell Wall Synthesis Inhibitors  
 Penicillins  
 amoxicillin (AMOXIL POLYMOX®)  
 ampicillin (PRINCIPEN®, OMNIPEN®) 55  
 benzathine Penicillin G  
 benzyl Penicillin (PENICILLIN G®)  
 carbenicillin (GEOCILLIN®)  
 cloxacillin (CLOXAPEN®)  
 dicloxacillin (DYNAPEN®)  
 methicillin (STAPHICILLIN®) 60  
 mezlocillin  
 nafcillin (NAFCIL®, UNIPEN®)  
 oxacillin  
 phenoxymethyl Penicillin (PENICILLIN V®) 65  
 piperacillin (PIPRACH®)  
 ticarcillin (TICAR®)

Cephalosporins  
 1st generation:  
 cefazolin (ANCEF®, DEFZOL®)  
 cephalexin (KEFLEX®)  
 cephalothin (KEFLIN®)  
 2nd generation:  
 cefaclor (CECLOR®)  
 cefoxitin (MEFOXIN®)  
 cefpodoxime (VANTIN®)  
 cefuroxime (ZINACEF®, CEFTIN®)  
 loracarbef (LORABID®)  
 3rd generation:  
 cefoperazone  
 cefotaxime (CLAFORAN®)  
 cefotetan  
 ceftazidime (FORTAX®, TAXIDIME®,  
 TAZICEF®)  
 ceftriaxone (ROCEPHIN®)  
 vefizoxime (CEFIZOX®)  
 4th generation:  
 cefepime  
 Other beta-Lactams aztreonam (AZACTAN®)  
 clavulanic acid  
 imipenem (PRIMAXIN®)  
 meropenem (MERREM IV®)  
 sulbactam  
 Other Cell-Wall Synthesis Inhibitors bacitracin  
 cycloserine  
 fosfomicin (MONUROL®)  
 vancomycin (VANCOCIN®)  
 Agents Which Affect Cell Membranes  
 Polymixins  
 Colistimethate  
 Potymyxin B  
 Protein Synthesis Inhibitors  
 Amino glycosides  
 amikacin (AMIKIN®)  
 gentamicin (GARAMYCIN®)  
 kanamycin (KANTREX®)  
 neomycin  
 netilmicin (NETROMYCIN®)  
 streptomycin  
 tobramycin  
 Tetracyclines  
 demeclocycline (DECLOMYCIN®)  
 doxycycline  
 doxycyclmine (VIBRAMYCIN®, DORYX®)  
 tetracycline (ACHROMYCIN®)  
 Macrolides  
 azithromycin (ZITHROMAX®)  
 clarithromycin (BIAXIN®)  
 erythromycin esters erythromycin  
 Other Protein Synthesis Inhibitors  
 Chloramphenicol (CHLOROMYCETIN®)  
 Clindamycin (CLEOCIN®)  
 Spectinomycin (TROBICIN®)  
 Inhibitors of Folate-Dependent Pathways  
 co-trimoxazole  
 silver Sulfadiazine  
 sodium Sulfacetamide  
 sulfamethoxazole (GANTANOL®)  
 sulfasalazine (AZULFIDINE®)  
 (SALICYLAZOSULFAPYRIDINE®)  
 sulfisoxazole (GANTRISIN®)  
 sulfonamides  
 Dihydrofolate Reductase Inhibitor  
 trimethoprim

DNA Gyrase Inhibitors  
 ciprofloxacin (CIPRO®)  
 gatifloxacin (TEQUIN®)  
 levofloxacin (LEVAQUIN®)  
 lomefloxacin (MAXAQUIN®)  
 nalidixic acid  
 ofloxacin (FLOXIN®)  
 Urinary Tract Antiseptics  
 nitrofurantoin  
 Antimycobacterial Agents  
 First-line anti-TB medicaments  
 ethambutol  
 isoniazid (INI-I®)  
 pyrazinamide  
 rifampin (RIMACTANE®)  
 streptomycin  
 Second-line anti-TB medicaments  
 capreomycinA  
 cycloserine  
 dapson  
 ethionamide  
 para-aminosalicylic acid  
 AntiFungal Agents  
 amphotericin B (FUNGIZONE®, AMPHOTEC®)  
 clotrimazole (MYCELEX®)  
 fluconazole (DIFLUCAN®)  
 flucytosine  
 griseofulvin  
 itraconazole (SPORANOX®)  
 ketoconazole (NIZORAL®)  
 miconazole (MONISTAT®)  
 nystatin (MYCOSTATIN®)  
 Antiparasitic Agents  
 Antimalarials  
 chloroquine (ARALEN®)  
 mefloquine (LARIAM®)  
 primaquine  
 pyrimethamine-sulfadoxine (FANSIDAR®)  
 Anti protozoals  
 metronidazole (FLAGYL®)  
 pentamidine isethionate  
 pyrimethamine-sulfonamide  
 trimethoprim (generic) sulfamethoxazole (GAN-  
 TANOL®)  
 Antihelminthic Medicaments  
 mebendazole  
 praziquantel (BILTRICIDE®)  
 pyrantel pamoate  
 thiabendazole (MINTEZOL®)  
 Antiviral Medicaments  
 acyclovir (ZOVIRAX®)  
 didanosine (DDI®)  
 foscarnet (FOSCAVIR®)  
 ganciclovir (DHPG®, CYTOVENE®)  
 ribavirin  
 rimantadine  
 stavudine (d4T)  
 valacyclovir (VALTREX®)  
 vidarabine (VIRA-A®)  
 zalcitabine (DDC®)  
 zidovudine (AZIDOTHYIMIDINE®, AZT®)  
 Protease inhibitors  
 indinavir (CRIXIVAN®)  
 ritonavir (NORVIR®)  
 saquinavir (FORTOVASE®)

Oncologic and Immunological Disorders  
 Breast Cancer  
 Lung Cancer  
 Colorectal Cancer  
 5 Prostate Cancer  
 Malignant Lymphomas  
 Ovarian Cancer  
 Acute Leukemias  
 Chronic Leukemias  
 10 Melanoma and other Skin Cancers  
 Hematopoietic Stem Cell Transplantation  
 Anti-Neoplastic Medicaments  
 Alkylating Agents  
 15 busulfan (MYLERAN®)  
 carboplatin (PARAPLATIN®)  
 carmustine (BNCU®, BiCNU®)  
 cisplatin (PLATINOL®)  
 cyclophosphamide (CYTOXAN®)  
 20 ifofamide (IFEX®)  
 lomustine (CCNU®, CeeNU®)  
 mechlorethamine (MUSTARGEN®)  
 meiphalan (ALKERAN®)  
 procarbazine (MATULANE®)  
 25 thiotepe  
 Antimetabolites  
 folic acid Antagonist  
 methotrexate  
 Purine Antagonists 6-mercaptapurine  
 30 6-thioguanine  
 Pyrimidine Antagonists  
 cytarabine (ARA-C®)  
 fluorouracil (5-FU®)  
 Hormonal Agents Hormones  
 35 diethylstilbestrol (DES®)  
 estrogens  
 prednisone (DELTASONE®)  
 Modulation of Hormone Release & Action Aminoglutethimide  
 40 leuprolide acetate  
 tamoxifen (NOLVADEX®)  
 Plant Alkaloids  
 Vinca Alkaloids  
 vinblastine (VELBAN®)  
 vincristine (Oncovin ONCOVIN®)  
 Podophyllotoxins  
 Etoposide (VP-16®)  
 Other  
 50 docetaxel (TAXOTERE®)  
 paclitaxel (TAXOL®)  
 Antibiotics  
 bleomycin (BLENOXANE®)  
 dactinomycin (COSMEGEN®)  
 daunorubicin (DAUNOXOME®)  
 55 doxorubicin (ADRIAMYCIN®)  
 mitomycin (MUTAMYCIN®)  
 Other Anti-neoplastic Medicaments  
 amsacrine (AMSA®)  
 azathioprine (IMURAN®)  
 60 capecitabine (XELODA®)  
 chlorambucil (LEUKERAN®)  
 cyclosporine (SANDIMMUNE®, NEORAL®)  
 gemcitabine (GEMZAR®)  
 hydroxyurea (HYDREA®)  
 65 mitotane (SODREN®)  
 mitoxantrone (NOVANTRONE®)  
 pamidronate (ARELIA®)

Immunosuppressant Medicaments  
 15-desoxyspergualin  
 corticosteroids  
 cyclosporine  
 Interferons  
 Interleukins  
 mycophenolate mofetil  
 sirolimus (RAPAMYCIN®)  
 tacrolimus  
 thalidomide  
 Nutritional Disorders  
 Malnutrition, vitamin and mineral deficiencies  
 Enteral Nutrition  
 Obesity  
 orlistat (XENICAL®)  
 appetite suppressants  
 sympathomimetic stimulants  
 amphetamine stimulants  
 Mineral supplementation  
 calcium ion iodine  
 iron  
 magnesium ion  
 phosphorous  
 potassium ion  
 selenium  
 sodium ion  
 zinc  
 Fat-soluble vitamins  
 vitamin A  
 vitamin D  
 vitamin E  
 vitamin K  
 Water-soluble vitamins  
 vitamin C  
 thiamine (vitamin B1)  
 riboflavin (vitamin B2)  
 niacin (vitamin B3)  
 pyridoxine (vitamin B6)  
 folate  
 cyanocobalamin (vitamin B12)  
 Medicaments Used to Alleviate Symptoms of Allergic Rhinitis, Upper Respiratory Symptoms, Cough, Mild Aches and Pains  
 Nasal Decongestants  
 ephedrine  
 phenylephrine  
 phenylpropanolamine  
 pseudoephedrine  
 Antihistamines (Histamine-1 receptor antagonists)  
 Antitussive agents  
 benzonatate  
 codeine  
 dextromethorphan  
 Expectorants  
 guaifenesin  
 iodinated glycerol  
 terpin hydrate  
 Xanthines  
 aminophylline  
 caffeine  
 dyphylline  
 theophylline  
 Pain relievers  
 narcotic agonists  
 NSAIDS  
 acetaminophen

Dietary Supplements  
 Arnica  
 Bilberry  
 Black Cohosh  
 5 Cat's claw  
 Chamomile  
 Echinacea  
 Evening Primrose Oil  
 Fenugreek  
 10 Flaxseed  
 Feverfew  
 Garlic  
 Ginger root  
*Ginkgo biloba*  
 Ginseng  
 15 Goldenrod  
 Hawthorn  
 Kava-Kava  
 Licorice  
 Milk thistle  
 20 Psyllium  
 Rauwolfia  
 Senna  
 Soybean  
 St. John's wort  
 25 Saw palmetto  
 Turmeric  
 Valerian  
 Therapeutic Proteins and Biotechnology Medicaments  
 Additional Agents: NORVACS®, NEURONTIN®,  
 30 PAXIL®, AUGMENTIN®, PROPECIA®, LAMISIL®,  
 LESCOL®, bisphosphonate.  
 Other Drugs  
 abacavir sulfate  
 acetazolamide  
 35 acetylsalicylic acid  
 albendazole  
 allopurinol  
 amiloride hydrochloride  
 amitriptyline hydrochloride artemether  
 40 atropine sulfate  
 benznidazole  
 biperiden hydrochloride  
 chloroquine phosphate  
 chlorpheniramine maleate  
 45 chlorpromazine hydrochloride  
 cimetidine  
 ciprofloxacin hydrochloride  
 clofazimine  
 clomiphene citrate  
 50 clomipramine hydrochloride  
 cloxacillin sodium  
 codeine phosphate  
 dapsone  
 didanosine  
 55 diethylcarbamazine citrate  
 digoxin  
 diloxanide furoate  
 DL-methionine  
 Doxycycline  
 60 Efavirenz  
 ergometrine maleate  
 ergotamine tartrate  
 erythromycin ethyl succinate  
 ethambutol hydrochloride  
 65 ethosuximide  
 ferrous sulfate  
 alendronate sodium

amlodipine besylate  
 amphetamine (mixed salts)  
 atorvastatin calcium  
 benazepril hydrochloride  
 bisoprolol fumarate  
 bupropion hydrochloride  
 carbidopa  
 cefprozil  
 cetirizine hydrochloride  
 citalopram hydrobromide  
 clindamycin hydrochloride  
 clonidine hydrochloride  
 clopidogrel bisulfate  
 cyclobenzaprine hydrochloride  
 desloratadine  
 digoxin  
 diltiazem hydrochloride  
 doxazosin mesylate  
 doxycycline  
 enalapril maleate  
 fexofenadine hydrochloride  
 fluoxetine hydrochloride  
 folic acid  
 fosinopril sodium  
 hydrocodone bitartrate  
 hydrocodone  
 hydroxyzine hydrochloride  
 indinavir  
 irbesartan  
 isosorbide mononitrate  
 lamivudine  
 levothyroxine sodium  
 lopinavir  
 loratadine  
 losartan potassium  
 meclizine hydrochloride  
 medroxyprogesterone acetate  
 meperidine  
 metformin hydrochloride  
 methylphenidate hydrochloride  
 methylprednisolone  
 metoclopramide hydrochloride  
 minocycline hydrochloride  
 montelukast sodium  
 naproxen sodium  
 nelfinavir  
 nevirapine  
 niclosamide  
 nicotinamide  
 nifurtimox  
 nitrofurantoin  
 nortriptyline hydrochloride  
 oxybutynin chloride  
 oxycodone hydrochloride  
 paracetamol  
 paroxetine hydrochloride  
 penicillin V potassium  
 phenytoin sodium  
 pioglitazone hydrochloride  
 prednisolone  
 primaquine phosphate  
 pravastatin sodium  
 prednisolone  
 promethazine hydrochloride  
 promethazine fumarate  
 propylthiouracil  
 pyrantel embonate

pyridostigmine bromide  
 raloxifene hydrochloride  
 ranitidine hydrochloride  
 rifampicin  
 5 risedronate sodium  
 risperidone  
 rosiglitazone maleate  
 salbutamol sulfate  
 saquinavir mesylate  
 10 sertraline hydrochloride  
 sildenafil citrate  
 sulfadiazine  
 sumatriptan succinate  
 tamoxifen citrate  
 tamsulosin hydrochloride  
 15 temazepam  
 terazosin hydrochloride  
 timolol maleate  
 tolterodine tartrate  
 tramadol hydrochloride  
 20 trazodone hydrochloride  
 triclabendazole  
 valacyclovir hydrochloride  
 valdecoxib  
 valproic acid  
 25 valsartan  
 venlafaxine hydrochloride  
 verapamil hydrochloride  
 warfarin sodium  
 zolpidem tartrate

30

## Examples XII

As can be seen above, various embodiments of the present invention can be utilized in specific medical applications. By way of example only and not by way of limitation, the present invention can be practiced to prepare delivery devices for use in chemotherapy to address/treat, by way of example and not by limitation, the following aspects of chemotherapy: psychological, timing (to coincide with tumor growth for example) route of administration, nausea, vomiting (CINV), compliance, and cost (e.g. reduce hospital management of patients, reduce the number of "repeat" drug doses due to patient vomiting, etc.). Still further, the just mentioned aspects are not limited to chemotherapy, as the present invention can be practiced to address common aspects between

45 chemotherapy and other treatments.  
 Further by way of examples, capsules containing Zofran (ondansetron), Temodar (temozolomide) can be made.

Still further, the present invention can be used in cardiovascular treatments, for example hypertension, heart failure, and heart rhythm disorders. Also, the present invention can be used in immunology (e.g. transplant rejections, auto-immune disorders, etc.). The present invention can be used to treat neurological disorders (such as Parkinson's disease, dementia, stroke, epilepsy, and migraine headache, etc.), psychiatric disorders (schizophrenia, bipolar disease, depression, anxiety, ADHD/ADD, Addictions, etc.), infectious diseases (fungal, bacterial, viral (HIV), etc.), and in anesthesiology (induction anesthesia, local anesthesia). Furthermore, the present invention has application in endocrinology (cholesterol, diabetes, hormone replacement therapy, thyroid dysfunction, oral contraception, obesity, etc.), dermatology (onychomycosis, acne, rosacea, psoriasis, etc.), rheumatology (arthritis, gout, osteoporosis/Osteomalacia), respiratory fields (asthma, emphysema, cystic fibrosis, etc.), gastro-intestinal fields

60 (gastroesophageal reflux disease, ulcer prophylaxis, crohn's disease, inflammatory bowel disease, etc.), chronic renal failure (vitamin and mineral replacement, blood pressure regu-

65

lation, diabetes, depression, etc.), genito-urinary (enlarged prostate/BPH, overactive bladder, erectile dysfunction, feminine yeast infections, etc.) and hematology-oncology (thromboembolous, hermatopoeisis, neoplastic disease, nausea/vomiting).

## Examples XIII

The present invention can be utilized with a variety of excipients. Categories of excipients include, but are not limited to, Binders, Disintegrants Fillers (diluents), Lubricants, Glidants (flow enhancers), Compression aids, Colors, Sweeteners, Preservatives, Suspending/dispersing agents, Film formers/coatings, Flavors, and Printing inks. Still further by way of example and not by limitation, the present invention can be utilized with the following excipients:

Magnesium Stearate	Titanium Dioxide
Lactose	Stearic Acid
Microcrystalline Cellulose	Sodium Starch Glycolate
Starch (corn)	Gelatin
Silicon Dioxide	Talc
Sucrose	Croscarmellose
Calcium Stearate	Hydroxy Propyl Cellulose
Povidone	Ethylcellulose
Pretzelatinized Starch	Calcium Phosphate (dibasic)
Hydroxy Propyl Methylcellulose	Crospovidone
OPA products (coatings & inks)	Shellac (and Glaze)

## Examples XIV

Examples of the supporting nutraceutical formulations are to illustrate examples where specific categories of the natural products industry can be utilized with the present invention. There are many more categories than the ones that are listed and therefore this is for simply for the purpose to show that the technology is broad and could be utilized for many specific categories. The specific mg of each product is not included due to the amounts of each material is typically based upon the formulators opinions, however there are some (RDA) recommended daily allowances that could be used to determine the formulation.

Category: Antioxidant

Primary Capsule:

d alpha Tocopherol  
Beta Carotene  
Tocotrioneol  
Grape Seed Oil

Secondary Capsule:

Selenium  
Vitamin C Ester

Category: Brain Support

Primary Capsule:

d alpha Tocopherol  
DHA  
Omega 3  
Lecithin  
Choline

Secondary Capsule:

Coenzyme Q 10  
*Ginkgo Biloba*  
B12

Category: Mood Support

Primary Capsule:

D alpha Tocopherol  
Lecithin

DHA

Omega 3

Secondary Capsule:

SAME

5 L Tyrosine

Category: Cardio Support

Primary Capsule:

d alpha Trocopherol  
Tocotrienol

10 Flax Oil Omega 6

Fish Oil Omega 3

Secondary Capsule:

Calcium

15 Magnesium

Coenzyme Q 10

Category: Diet Support

Primary Capsule:

Conjugated Linolic Acid

20 Flax Seed Oil

Secondary Capsule:

Chromium  
Zinc

L Carnitine

25 Category: Immune Support

Primary Capsule:

Garlic Oil  
Olive Leaf Oil  
d alpha Tocopherol

30 Secondary Capsule:

Zinc  
Echinacea

Category: Laxative Support

Primary Capsule:

35 *Aloe Vera*

Flax Seed Oil

Secondary Capsule:

Senna Leaf  
Psyllium

40 Category: Prostate Support

Primary Capsule:

Saw Palmetto Oil  
Pygeum Oil  
Flaxseed Oil

45 Pumpkin Seed Oil

Secondary Capsule:

Selenium  
Zinc  
*Boswellia Serrata*

50 Category: Inflammation Support

Primary Capsule:

*Boswellia Serrata* Oil  
Guggul Oil  
Omega 3 Oil

55 Ginger Oil

Secondary Capsule:

Curcumin  
Holy Basil

Category: Sports Nutrition/Muscle Support

60 Primary Capsule:

Conjugated linolic Acid  
MCT Oil

Secondary Capsule:

Zinc

65 Chromium

*Tribulus Terrestris*

19 Nor-5-Androstendione

Category: Menopause Support

Primary Capsule:

Evening Primrose Oil

Red Raspberry Oil

Secondary Capsule:

Licorice Root

Black Cohosh

Soy Isoflavones

Category: Cholesterol Support

Primary Capsule:

Sterol Esters

Guggul Oil

d alpha Tocopherol

Tocotrienol

Secondary Capsule:

Garlic Extract

Zinc

From the above discussion, it will be appreciated that the present invention provides novel integrated capsule delivery apparatus and methods for delivering diverse physical states (e.g., solid, liquid, gas or dispersion) of a single active ingredient or medicament (e.g., pharmaceutical, biotechnical, nutraceutical, vitamin, dietary supplement, mineral or combination thereof), or a plurality of active ingredients or medicaments, in a single dosage capsular form, wherein at least two of the active ingredients or medicaments if different receiving chambers have physical states that differ. In preferred design, the encapsulation processes and multi-compartment capsular technology of the present invention may include various desirable properties such as, for example, controlling time-release of key active ingredients or medicaments, prolonging shelf-life of the active ingredients or medicaments, improving palatability, reducing overall production costs and reducing the number of capsules consumed by a patient or consumer as nutritional or therapeutic agents.

The present invention provides novel integrated capsule delivery apparatus and methods for delivering a single dosage, multi-compartment capsule comprising a capsular base and cap configuration, wherein the size and shape of the cap, relative to its sealing relationship with the base, generally eliminates or substantially reduces any potential dead space volume within the internal periphery, of the capsule, thereby functionally negating the opportunity for reaction between an air bubble and one or more active ingredients introduced into the capsule and, accordingly, improving stability of the capsular ingredient(s).

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative, and not restrictive. The scope of the invention is, therefore, indicated by the appended claims, rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed and desired to be secured by United States Letters Patent is:

1. A multi-compartment capsule, comprising: a first receiving chamber comprising at least one ingredient having a first physical state, and a second receiving chamber comprising at least one ingredient having a second physical state,

wherein the first physical state of the ingredient of the first receiving chamber is different from the second physical state of the ingredient of the second receiving chamber, and

wherein the ingredients are pharmaceuticals, medicaments, nutraceuticals, botanicals, extracts, antioxidants, phospholipids, herbal oils, marine oils, vitamins, miner-

als, carotenoids, hormones, proteins, amino acids, specialty nutrients, probiotics, enzymes, brain support components, mood support components, cardio support components, diet support components, immune support components, laxative support components, inflammation support components, prostate support components, sports nutrition components, menopause support components, cholesterol support components, or mixtures thereof.

2. The multi-compartment capsule of claim 1, wherein the antioxidants comprise: d-alpha tocopherol, beta carotene, tocotrienol, grape seed oil, selenium, vitamin C, or mixtures thereof.

3. The multi-compartment capsule of claim 1, wherein the brain support components comprise: d-alpha tocopherol, docosahexaenoic acid (DHA), Omega 3 fatty acids, lecithin, choline, coenzyme Q 10, *Ginkgo biloba*, vitamin B 12, or mixtures thereof.

4. The multi-compartment capsule of claim 1, wherein the mood support components comprise: d-alpha tocopherol, lecithin, docosahexaenoic acid (DHA), Omega 3 fatty acids, S-Adenosylmethione (SAM-e), l-tyrosine, or mixtures thereof.

5. The multi-compartment capsule of claim 1, wherein the cardio support components comprise: d-alpha tocopherol, tocotrienol, flax oil, fish oil, Omega 6 fatty acids, Omega 3 fatty acids, calcium, magnesium, coenzyme Q 10, or mixtures thereof.

6. The multi-compartment capsule of claim 1, wherein the diet support components comprise: conjugated linoleic acid, flax seed oil, chromium, zinc, l-carnitine, or mixtures thereof.

7. The multi-compartment capsule of claim 1, wherein the immune support components comprise: garlic oil, olive leaf oil, d-alpha tocopherol, zinc, Echinacea, or mixtures thereof.

8. The multi-compartment capsule of claim 1, wherein the prostate support components comprise: saw palmetto, pygeum oil, flax seed oil, pumpkin seed oil, selenium, zinc, *Boswellia serrata* extract or oil, or mixtures thereof.

9. The multi-compartment capsule of claim 1, wherein the inflammation support components comprise: *Boswellia serrata* extract or oil, guggul oil, Omega 3 oil, ginger oil, curcumin, Holy Basil, or mixtures thereof.

10. The multi-compartment capsule of claim 1, wherein the sports nutrition components comprise: conjugated linoleic acid, medium chain triglycerides oil (MCT oil), zinc, chromium, *Tribulus terrestris*, 19-nor-d-androstendione, or mixtures thereof.

11. The multi-compartment capsule of claim 1, wherein the menopause support components comprise: Evening primrose oil, red raspberry oil, licorice root, black cohosh, soy isoflavones, or mixtures thereof.

12. The multi-compartment capsule of claim 1, wherein the cholesterol support components comprise: sterol esters, guggul oil, d-alpha tocopherol, tocotrienol, garlic extract, zinc or mixtures thereof.

13. The multi-compartment capsule of claim 1, wherein the extracts comprise: bilberry, black cohosh, cinnamon, dandelion, forskolin, turmeric, green tea, ginseng, fennel seed, fenugreek, curcumin, guarana, garlic, glucosamine, gotu kola, grape seed, ma huang, hesperidin, red rice yeast, spirulina, saw palmetto, St. John's Wort, yohimbe, yohimbine, valerian, kava kava, chamomile, quercetin, oregano, sage, saw palmetto, lavender, or mixtures thereof.

14. The multi-compartment capsule of claim 1, wherein the ingredients consist essentially of: anticholinergics, anti-nauseants, anti-vertigo agents, histamine-1 receptor antagonists, proton-pump inhibitors, dopamine antagonists, prokinetic

gastric stimulants, serotonin 5 HT3 receptor antagonists, corticosteroids, antihistamines, benzodiazepines, cannabinoids, or mixtures thereof.

15. The multi-compartment capsule of claim 14, wherein the ingredients consist essentially of: a serotonin 5 HT3 5 receptor antagonist and a cannabinoid.

16. The multi-compartment capsule of claim 15, wherein the serotonin 5 HT3 receptor antagonist comprises: dolasetron, granisetron, or ondansetron.

17. The multi-compartment capsule of claim 1, further 10 comprising a third receiving chamber for incorporating at least one ingredient that is different from the ingredients in the first and second receiving chambers.

\* \* \* \* \*

UNITED STATES PATENT AND TRADEMARK OFFICE  
**CERTIFICATE OF CORRECTION**

PATENT NO. : 9,241,911 B2  
APPLICATION NO. : 14/036521  
DATED : January 26, 2016  
INVENTOR(S) : Fred H. Miller

Page 1 of 1

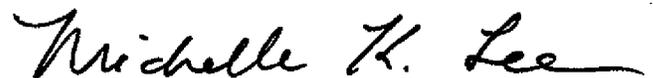
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

Claims

In column 94, claim 4, line 22, please replace "I-tyrosine" with --l-tyrosine--

In column 94, claim 6, line 31, please replace "I-carnitine" with --l-carnitine--

Signed and Sealed this  
Third Day of May, 2016



Michelle K. Lee  
*Director of the United States Patent and Trademark Office*